DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Parts 317, 381, and 412

[Docket No. FSIS 2022–0015]

RIN 0583–AD87

Voluntary Labeling of FSIS-Regulated Products With U.S.-Origin Claims

AGENCY: Food Safety and Inspection Service (FSIS), U.S. Department of Agriculture (USDA).

ACTION: Final rule.

SUMMARY: FSIS is amending its regulations to define the conditions under which the labeling of meat, poultry, and egg products under mandatory inspection, as well as voluntarily inspected products, may bear voluntary label claims indicating that the product is of United States origin. As of the compliance date of this final rule, establishments will not need to include these claims on the label, but if they choose to include them, they will need to meet the requirements in this rule.

DATES:

Effective date: May 17, 2024.

Compliance date: Establishments choosing to include voluntary U.S.-origin claims on the labels of FSIS-regulated products will need to comply with the new regulatory requirements under 9 CFR 412.3 on the next uniform compliance date for new labeling regulations, January 1, 2026.

Comment date: Submit comments on the revised FSIS Guideline for Label Approval on or before May 17, 2024.

ADDRESSES: A downloadable version of the revised FSIS Guideline for Label Approval is available to view and print at *https://www.fsis.usda.gov/guidelines/2024-0001*.

FSIS invites interested persons to submit comment on the revised FSIS Guideline for Label Approval. Comments may be submitted by one of the following methods.

- *Federal eRulemaking Portal:* This website 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 *https://www.regulations.gov*. Follow the on-line instructions at that site for submitting comments.
- *Mail:* Send to Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, 1400 Independence Avenue SW, Mailstop 3758, Washington, DC 20250–3700.

Instructions: All items submitted by mail or electronic mail must include the Agency name and docket number FSIS–2022–0015. Comments received in response to this docket will be made available for public inspection and posted without change, including any personal information, to *https://www.regulations.gov*.

Docket: For access to background documents or comments received, call (202) 720–5046 to schedule a time to visit the FSIS Docket Room at 1400 Independence Avenue SW, Washington, DC 20250–3700.

FOR FURTHER INFORMATION CONTACT: Rachel Edelstein, Assistant Administrator, Office of Policy and Program Development, by telephone at (202) 937–4272.

SUPPLEMENTARY INFORMATION:

Executive Summary

After considering the comments received on the proposed rule discussed below, FSIS is finalizing its March 13, 2023, proposal to define the conditions under which meat, poultry, and egg products, as well as voluntarily inspected products, may bear voluntary label claims indicating that the product is of United States origin (88 FR 15290).

The final rule is consistent with the proposed rule with four changes. FSIS is revising the proposed regulatory text to: (1) clarify the conditions under which voluntary U.S. State, Territory, and locality-origin label claims may be made; (2) clarify the conditions under which use of the U.S. flag, or a U.S. State or Territory flag, on such voluntary labels may be made; (3) make a few minor editorial changes to the regulatory text to improve readability and clarity; and (4) revise the regulations in 9 CFR 317.8(b)(1) and 381.129(b)(2), relating to labeling that indicates a product's geographic significance or locality, to clarify how these existing regulatory requirements align with the new requirements in 9 CFR 412.3 for the voluntary display of U.S.-origin claims.

The final rule will amend FSIS labeling regulations at 9 CFR part 317, Labeling, Marking devices, and Containers; 9 CFR part 381, Poultry Products Inspection Regulations; and 9 CFR part 412, Label Approval. Under the final rule, two specific voluntary U.S.-origin label claims, ''Product of USA'' and ''Made in the USA'' (referred to in the proposed rule as ''authorized claims'' (88 FR 15290)), will be generically approved [1] for use on single ingredient FSIS-regulated products (*i.e.,* products produced under FSIS mandatory or voluntary inspection services) derived from animals born, raised, slaughtered, and processed in the United States. The two voluntary label claims ''Product of USA'' and ''Made in the USA'' will also be generically approved for use on multi-ingredient FSIS-regulated products if: (1) All FSIS-regulated products in the multi-ingredient product are derived from animals born, raised, slaughtered, and processed in the United States; (2) all other ingredients, other than spices and flavorings, are of domestic origin; and (3) the preparation and processing steps for the multi-ingredient product have occurred in the United States.

Also consistent with the proposed rule, 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 (referred to in the proposed rule as ''qualified claims'' (88 FR 15290, 15291) will be generically approved for use,[2] but such claims will need to include the preparation and processing steps (including slaughter) that occurred in the United States upon which the claim is made.

Further consistent with the proposed rule, the final rule will apply to products sold in the domestic market.[3] For products exported from the United States, FSIS will continue to verify that labeling requirements for the applicable country are met, as shown in the FSIS Export Library.[4]

These final regulations ensure labels bearing these claims are not false or misleading (9 CFR 317.8(a), 381.129(b), 590.411(f)(1)). The Federal Meat Inspection Act, the Poultry Products Inspection Act, and the Egg Products Inspection Act prohibit false or misleading labeling of regulated products. The final regulatory definitions of voluntary U.S.-origin

[1] Labels that are generically approved under the FSIS regulations may be used in commerce without prior submission to the Agency for approval. Products must bear all required labeling features and comply with the Agency's labeling regulations to be eligible for generic approval (9 CFR 412.2(a)(1)). Current FSIS regulations allow all geographic and country of origin claims on labels of FSIS-regulated products to be generically approved (9 CFR 412.2(b)).

[2] On January 18, 2023, FSIS finalized a rule to allow generic approval of the labels of voluntarily inspected products (88 FR 2798). In 2020, FSIS finalized a rule to allow generic approval for egg product labels (85 FR 68640, October 29, 2020; see 9 CFR 590.412).

[3] As explained in the proposed rule (88 FR 15290, 15292), currently, when products imported into the U.S. are repackaged or otherwise reprocessed in a FSIS-inspected facility, they are deemed and treated as domestic product for labeling purposes. Therefore, such imported products will be subject to these regulatory requirements.

[4] FSIS Export Library, available at: *https://www.fsis.usda.gov/inspection/import-export/import-export-library*.

claims align the meaning of those claims with consumers' understanding of the information conveyed by those claims. This final rule enables informed purchasing decisions by providing information that is valued by consumers. This final rule will reduce the market failures associated with incorrect and misleading information.

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I. Background

FSIS is responsible for ensuring that meat, poultry, and egg products are safe, wholesome, and properly labeled and packaged. The Agency administers a regulatory program for meat products under the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601 *et seq.*), for poultry products under the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451 *et seq.*), and for egg products under the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031 *et seq.*). FSIS also provides voluntary reimbursable inspection services under the Agricultural Marketing Act (AMA) (7 U.S.C. 1622 and 1624) for eligible products not requiring mandatory inspection under the FMIA, PPIA, and EPIA.[5]

Under the FMIA, PPIA, and EPIA, any meat, poultry, or egg product is misbranded if its labeling is false or misleading in any particular (21 U.S.C. 601(n)(1); 21 U.S.C. 453(h)(1); 21 U.S.C. 1036(b)). In particular, no product or any of its wrappers, packaging, or other containers shall bear any false or misleading marking, label, or other labeling and no statement, word, picture, design, or device which conveys any false impression or gives any false indication of origin or quality or is otherwise false or misleading shall appear in any marking or other labeling (9 CFR 317.8(a)), 381.129(b), 590.411(f)(1)). FSIS has similar authority under the AMA concerning the false or misleading labeling of products receiving voluntary inspection services (7 U.S.C. 1622(h)(1)).

On March 13, 2023, FSIS published a proposed rule to define the conditions under which the labeling of meat, poultry, and egg products, as well as voluntarily inspected products, may bear voluntary label claims indicating that the product is of United States origin (88 FR 15290). FSIS published the proposed rule because it determined that its existing labeling policy may have confused consumers about the origin of FSIS-regulated products in the U.S. marketplace (88 FR 15290, 15292*).* The proposed rule also responded to the call for a rulemaking on voluntary ''Product of USA'' labeling for meat products in President Biden's Executive Order 14036, *Promoting Competition in the American Economy* (88 FR 36987, July 14, 2021; 88 FR 15290, 15292).

As explained in the proposed rule, FSIS received three petitions from industry associations regarding the origin of meat products bearing the ''Product of USA'' label claim, each generally asserting that the Agency's current policy on U.S.-origin labeling furthers consumer confusion as to whether products with U.S.-origin claims are derived from animals born, raised, slaughtered, and processed in the United States (88 FR 15290, 15292). In June 2018, FSIS received a petition, submitted on behalf of the Organization for Competitive Markets (OCM) and the American Grassfed Association (AGA), requesting that FSIS amend its labeling policy to state that meat products may be labeled as ''Product of USA'' only if ingredients having a bearing on consumer preference, such as meat, vegetables, fruits, and dairy products, are of domestic origin. In October 2019, the United States Cattlemen's Association (USCA) submitted a petition requesting that FSIS amend its labeling policy to state that any beef product voluntarily labeled as ''Made in the USA,'' ''Product of the USA,'' ''USA Beef,'' or with similar claims, be derived from cattle that have been born, raised, and slaughtered in the United States. Both the OCM/AGA and USCA petitions asserted that FSIS' current policy is misleading to consumers. FSIS received 2,593 public comments on the OCM/AGA petition and 111 public comments on the USCA petition. A majority of comments received on both petitions supported the respective petitions. In March 2020, FSIS responded to both petitions to state the Agency's conclusion that its current labeling policy may be causing confusion in the marketplace and that FSIS had decided to initiate rulemaking to define the conditions under which the labeling of meat products would be permitted to bear voluntary U.S.-origin claims. Finally, in June 2021, the National Cattlemen's Beef Association (NCBA) submitted a petition requesting that FSIS amend its regulations to eliminate the broadly applicable ''Product of USA'' label claim but to allow for other label claims. Specifically, the petition requested that FSIS amend its regulations to state that single ingredient beef products or ground beef may be labeled as ''Processed in the USA.'' FSIS received 261 public comments on the NCBA petition, with most comments not in support of the petition. As explained in the proposed rule, the publication of the proposed rule served as the Agency's response to the issues raised by all three related petitions (88 FR 15290, 15294).

After receiving the petitions, to inform rulemaking on voluntary ''Product of USA'' labeling, FSIS conducted a comprehensive review of the Agency's current voluntary ''Product of USA'' labeling policy to help determine what the ''Product of USA'' label claim means to consumers. To gather information as part of FSIS' comprehensive review, RTI International conducted a consumer web-based survey (''RTI survey'' or ''survey'') on ''Product of USA'' labeling.[6] As explained in the proposed rule, the combined survey results show that most consumers believe that ''Product of USA'' label claims indicate that the product is derived from animals

[5] These voluntary reimbursable inspection services include activities related to export certification (9 CFR 350.3(b), 362.2(b), and 592.20(d)); products containing meat and poultry that are not under mandatory FSIS inspection (9 CFR 350.3(c) and 362.2(a)); voluntary inspection of certain non-amenable species (9 CFR part 352, subpart A and 9 CFR part 362); and voluntary inspection of rabbits (9 CFR part 354).

[6] Cates, S. et al. 2022. Analyzing Consumers' Value of ''Product of USA'' Label Claims. Contract No. GS–00F–354CA. Order No. 123–A94–21F–0188. Prepared for Andrew Pugliese. The final report and a copy of the survey itself can be found on FSIS' website at: *https://www.fsis.usda.gov/sites/default/files/media_file/documents/Product_of_USA_Consumer_Survey_Final_Report.pdf.*

born, raised, slaughtered, and processed in the United States (88 FR 15290, 15295), and that a majority of consumers believe that the current FSIS ''Product of USA'' label claim is misleading as to the actual origin of FSIS-regulated products. Further, as discussed below, most of the comments received on the proposed rule supported the proposed rule, with many individuals and domestic trade associations citing the need for accurate labeling to ensure that FSIS-regulated products labeled as ''Product of USA'' or ''Made in the USA'' are derived from animals born, raised, slaughtered, and processed in the United States.

The proposed rule's comment period closed on June 11, 2023, 90 days after its publication.[7] Based on comments received on the proposed rule, the related petitions on the topic, and the consumer survey results, FSIS has determined that its current labeling policy may be misleading consumers because it does not align with consumers' understanding of the label and that adopting the proposed definition of the voluntary ''Product of USA'' and ''Made in the USA'' label claims will more accurately reflect its commonly understood meaning that the product was derived from an animal born, raised, slaughtered, and processed in the United States.

The final rule will enhance consumer purchasing decisions and ensure that the labeling is consistent with consumers' understanding and expectations of products labeled as ''Product of USA'' and ''Made in the USA'' and not misleading.

II. Final Rule

The final rule is consistent with the proposed rule with the four following changes.

FSIS is making four changes to the proposed new regulatory text in 9 CFR 412.3. First, in response to comments, FSIS is clarifying that voluntary label claims may be used under generic approval to designate the U.S. State, Territory, or locality-origin of a FSIS-regulated product or product component, provided that such claims meet the requirements for use of corresponding voluntary U.S.-origin claims under 9 CFR 412.3. Specifically, products labeled with ''Product of . . .'' or ''Made in the . . .'' claims referring to the origin of a U.S. State, Territory, or locality will need to meet the regulatory criteria under 9 CFR 412.3(a) and (b) for these claims (*e.g.,* a meat product labeled with the claim ''Product of Montana'' must be derived from an animal born, raised, slaughtered, and processed in Montana). Label claims other than ''Product of . . .'' or ''Made in the . . .'' that refer to the U.S. State, Territory, or locality-origin component of a FSIS-regulated products' preparation and processing will need to meet the regulatory criteria under 9 CFR 412.3(c) for these claims (*e.g.,* a pork product derived from an animal born, raised, and slaughtered in a foreign country, then sliced and packaged in Oklahoma, could be labeled with the claim ''Sliced and Packaged in Oklahoma''). These requirements for U.S. State, Territory, and locality-origin claims were discussed in the proposed rule, and FSIS originally proposed to clarify this policy in Agency guidance (88 FR 15290, 15296). However, in response to comments supporting the inclusion of these claims within the scope of the proposed rule and comments asking for clarification about the use of such claims, FSIS decided that changes to the regulatory text were warranted.

Second, in response to comments requesting FSIS to clarify when display of the U.S. flag on labels of FSIS-regulated products would be considered use of a voluntary U.S.-origin claim, the Agency is clarifying that label displays of the U.S. flag, or a U.S. State or Territory flag, on products will be considered use of voluntary origin claims of the United States or the respective U.S. State or Territory. Label displays of the U.S. flag, or a U.S. State or Territory flag, are inherently claims indicating a product's origin. Therefore, requirements for such displays are logical outgrowths of the proposed requirements for the voluntary labeling of FSIS-regulated products with U.S.-origin claims.

Specifically, FSIS is revising 9 CFR 412.3 to clarify that the voluntary use of a standalone image of the U.S. flag, or a U.S. State or Territory flag, will need to meet the requirements under 9 CFR 412.3(a) and (b) for use of voluntary ''Product of . . .'' and ''Made in . . .'' claims (*e.g.,* a meat product labeled with a standalone display of the U.S. flag will need to be derived from an animal born, raised, slaughtered, and processed in the United States). The voluntary use of the U.S. flag, or a U.S. State or Territory flag, may be used to designate a specific origin of a product or component of the product's preparation and processing but the image will need to be accompanied by a description of the preparation and processing steps that occurred in the United States, or the respective U.S. State or Territory, upon which the claim is being made (*e.g.,* display of the New York State flag on a pork product with the accompanying description ''Sliced and Packaged in New York'').

Third, FSIS is making a few editorial changes to the proposed regulatory text in 9 CFR 412.3 to improve readability and clarity.

Finally, FSIS is also revising the regulations in 9 CFR 317.8(b)(1) and 381.129(b)(2), relating to labeling that indicates a product's geographic significance or locality, to clarify how these existing regulatory requirements align with the new requirements in 9 CFR 412.3 for the voluntary display of U.S.-origin claims.

As explained above, under the final rule, the two claims ''Product of USA'' and ''Made in the USA'' may be displayed on labels of FSIS-regulated single ingredient products only if the product is derived from animals born, raised, slaughtered, and processed in the United States, or in the case of a multi-ingredient product, if: (1) All FSIS-regulated products in the multi-ingredient product are derived from an animal born, raised, slaughtered, and processed in the United States; (2) all other ingredients, other than spices and flavorings, are of domestic origin; and (3) the preparation and processing steps for the multi-ingredient product have occurred in the United States. Before January 1, 2026, the compliance date for the new regulatory requirements,[8] FSIS will update its Food Standards and Labeling Policy Book [9] to remove the current ''Product of USA'' entry that allows FSIS-regulated products that are minimally processed in the United States to be labeled as ''Product of USA.''

Additionally, the final rule will allow for claims other than the two claims ''Product of USA'' and ''Made in the USA'' to be displayed on labels to indicate the U.S.-origin of a component of a product's preparation and processing. Label claims other than ''Product of USA'' or ''Made in the USA'' that indicate that a component of a FSIS-regulated product's preparation and processing is of U.S. origin will be allowed under the final rule, but such claims will need to include the preparation and processing steps that

[7] The original comment period closed on May 12, 2023. FSIS extended the comment period by 30 days in response to requests from a foreign country and a domestic trade association for additional time to determine and formulate comments on the impact of the proposed regulations. See FSIS Constituent Update, April 7, 2023, available at: *https://www.fsis.usda.gov/news-events/news-press-releases/constituent-update-april-7-2023.*

[8] See 87 FR 77707, December 20, 2022.

[9] Available at: *https://www.fsis.usda.gov/guidelines/2005-0003.*

occurred in the United States upon which the claim is made.

FSIS Labeling and AMS Mandatory COOL

This final rule will not alter or affect any other Federal statute or regulation relating to country of origin labeling requirements. For example, as explained in the proposed rule, the regulatory requirements established by this final rule will not conflict with the requirements of the USDA Agricultural Marketing Service's (AMS) Country of Origin (COOL) mandatory labeling regulations (88 FR 15290, 15296; see also 7 CFR part 60 and 65). Establishments choosing to use voluntary U.S.-origin labels on products covered by this final rule will still need to comply with applicable COOL requirements (see 9 CFR 317.8(b)(40)) for the identification of country of origin, for commodities subject to the COOL requirements.

FSIS' current labeling regulations require that a country of origin statement on the label of any meat ''covered commodity'' as defined in 7 CFR part 65, subpart A, that is to be sold by a ''retailer,'' as defined in 7 CFR 65.240, must comply with the COOL requirements in 7 CFR 65.300 and 65.400.[10] Under this final rule, any commodity that is subject to COOL mandatory country of origin labeling must continue to comply with those requirements.

Required Documentation To Support Claims

Consistent with the proposed rule, official establishments and facilities choosing to use a U.S.-origin claim on labels of FSIS-regulated products 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 as the regulations require for the use of all generically approved labels (88 FR 15290, 15296; see 9 CFR 412.2(a)(1)). FSIS will accept existing documentation to demonstrate compliance with the applicable regulatory requirements. 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.

[10] 9 CFR 317.8(b)(40) and 9 CFR 381.129(f). FSIS notes that the Agency's proposed regulatory requirements would concern voluntary label claims displayed on FSIS-regulated products, while COOL requires mandatory country of origin disclosure in the form of a placard, sign, label, sticker, band, twist tie, pin tag, or other format to consumers of covered commodities (See 7 CFR 65.300(a) and 65.400(a)).

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 eggs, 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 eggs, 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.

Regulated entities choosing to make voluntary U.S.-origin claims other than ''Product of USA'' and ''Made in the USA'' under the final rule in 9 CFR 412.3(c) may have:

- A written description of the controls used in each applicable preparation and processing step of source animals and eggs, all additional ingredients other than spices and flavorings, and resulting products to ensure that the U.S.-origin claim complies with the regulatory criteria. The described controls may include those used to trace and, as necessary, segregate, during each applicable preparation or processing step, source animals and eggs, all additional ingredients other than spices and flavorings, and resulting products that comply with the U.S.-origin claim from those that do not comply; or
- A signed and dated document describing how the U.S.-origin claim regarding the preparation and processing steps is not false or misleading.

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). FSIS has also updated its FSIS Guideline for Label Approval [11] on the use of voluntary U.S.-origin labels eligible for generic approval, to provide more examples of the types of documentation that official establishments and facilities may maintain to support use of the claims.

[11] Available at: *https://www.fsis.usda.gov/guidelines/2024-0001*.

Compliance Date and Transition Period

As explained in the proposed rule, FSIS generally uses a uniform compliance date for new labeling regulations (88 FR 15290, 15297). The uniform compliance date is intended to minimize the economic impact of labeling changes by providing for an orderly industry adjustment to new labeling requirements that occur between the designated dates.[12] Per the uniform compliance date schedule, establishments voluntarily using a claim subject to this rulemaking will need to comply with the new regulatory requirements by January 1, 2026 (87 FR 77707, December 20, 2022). On that date and going forward, FSIS will consider as compliant only labels bearing the voluntary claims ''Product of USA,'' ''Made in the USA,'' and other U.S.-origin claims for FSIS-regulated products that comply with the codified requirements for the use of such claims in this final rule. Establishments may choose to voluntarily change their labels to comply with the final rule before January 1, 2026, and are encouraged to do so as soon as practicable after the publication of this final rule.

III. Summary of Comments and Responses

FSIS received 3,364 comments on the proposed rule from domestic and foreign trade associations, foreign countries, meat and poultry producers, dairy and crop producers, farmers, non-profit organizations, and consumers. Most of the comments were in support of the proposed rule. Specifically, over 3,000 consumers, and most domestic producers and organizations, supported the proposed rule, with many citing the need to revise the ''Product of USA'' or ''Made in the USA'' labeling claims policy to require that FSIS-regulated products labeled as ''Product of USA'' or ''Made in the USA'' are derived from animals born, raised, slaughtered, and processed in the United States. A few comments were outside the scope of the proposed rulemaking, as they concerned labeling issues not related to U.S.-origin claims (*e.g.,* the labeling of Halal-certified products and products containing genetically modified organisms).

A summary of the relevant issues raised by commenters and the Agency's responses follows.

[12] See FSIS *Uniform Date for Food Labeling Regulations Final Rule* (69 FR 74405, December 14, 2004).

A. ''Product of USA'' and ''Made in the USA'' Claims

Comment: One domestic trade association stated that the proposed rule is overly prescriptive and asked FSIS to consider establishing acceptable U.S.-origin label claim criteria through guidance.

Response: FSIS disagrees that the rule is overly prescriptive. Establishments are not required to use ''Product of USA'' or ''Made in the USA'' label claims. In addition, if the product does not meet the criteria for these claims, the final rule allows for other claims that describe the specific preparation and processing steps that occurred in the United States (9 CFR 412.3(c)). The Agency is taking this regulatory action to address consumer confusion surrounding current voluntary U.S.-origin label claims on FSIS-regulated products in the U.S. marketplace. As explained in the proposed rule, consumer survey results, reviews of consumer research, and comments received on related petitions indicated that the Agency's current ''Product of USA'' labeling policy is misleading to consumers (88 FR 15290). The fact that most comments received on the proposed rule supported the proposed voluntary U.S.-origin label claim requirements further demonstrates the need to amend the FSIS regulations to define the conditions under which the labeling of meat, poultry, and egg products, as well as voluntarily inspected products, may bear voluntary label claims indicating that the product is of U.S. origin.

Comment: One foreign trade association stated that the Agency failed to consider alternative criteria for the ''Product of USA'' or ''Made in the USA'' claims, such as a less rigorous requirement that the animal is only ''raised and slaughtered in the United States.'' This commenter stated that FSIS should withdraw the proposed rule or solicit additional comments to reconsider alternative criteria for the ''Product of USA'' and ''Made in the USA'' label claims. One foreign country stated that the RTI survey did not include consideration of alternative options to the proposed label claims. One domestic trade association stated that the proposed label claims should be replaced with a label claim such as ''Processed in the USA'' that would be more accurate and verifiable.

Response: The commenters incorrectly stated that FSIS failed to consider alternative criteria for the ''Product of USA'' and ''Made in the USA'' label claims, or that the RTI survey did not include consideration of alternative options for the label claims. FSIS reviewed alternative criteria for the claims. That review has led FSIS to establish the various options for label claims other than ''Product of USA'' and ''Made in the USA'' on single ingredient and multi-ingredient products. These other options allow for various claims regarding the U.S.-origin of FSIS-regulated products.

Further, as explained in the proposed rule, the RTI survey included questions that surveyed consumers' understanding of the meaning of the ''Product of USA'' label claim by showing participants possible definitions of the claim with various combinations of ''born,'' ''raised,'' ''slaughtered,'' and ''processed'' (88 FR 15290, 15295). The survey also included questions about consumers' willingness to pay for products bearing ''Product of USA'' label claims with different definitions on the spectrum of ''born,'' ''raised,'' ''slaughtered,'' and ''processed'' in the United States. The combined survey results show that most consumers believe that ''Product of USA'' label claims indicate that the product is derived from animals born, raised, slaughtered, and processed in the United States. This survey shows that a majority of consumers do not understand the current FSIS ''Product of USA'' label claim and that it is misleading to a majority of consumers as to the actual origin of FSIS-regulated products. These survey results informed the Agency's decision-making process for developing the proposed rule. FSIS considered other options but proposed the requirements that most closely reflected the meaning of the ''Product of USA'' and ''Made in USA'' claims based on the survey, the relevant petitions, and the comments received on those petitions. For these reasons, FSIS disagrees that the Agency should withdraw the proposed rule or replace the requirements for the voluntary ''Product of USA'' and ''Made in the USA'' claims.

Comment: A few domestic and foreign trade associations stated that the doctrine of substantial transformation should be the standard for determining a product's country of origin for ''Product of USA'' or ''Made in the USA'' claims, rather than the ''born, raised, processed, and slaughtered'' criteria. According to these commenters, under the substantial transformation doctrine, the origin of FSIS-regulated meat products would be the country of the animal's slaughter. One domestic trade association stated that products made from animals that were substantially transformed in the United States, such as through slaughter, should be eligible for the label claim ''Processed in the USA,'' which would be consistent with other regulatory standards. Another domestic trade association stated that the proposed rule should be revised to allow for the use of ''Product of USA'' or ''Made in the USA'' claims on any product derived from an animal that lived more than 95 percent of its life in the United States and is slaughtered, processed, and packaged in United States.

Response: As explained in the proposed rule, the Agency's consumer survey results show that most consumers believe the ''Product of USA'' label claim means the product was derived from animals born, raised, slaughtered, and processed in the United States (88 FR 15290, 15295). Most of the comments received on the proposed rule also supported the ''born, raised, processed, and slaughtered'' proposed definition for these claims. Based on these survey results and comments, the petition on this topic, and the comments received on those petitions, FSIS has determined that consumers believe that these claims mean that the product was derived from animals born, raised, slaughtered, and processed in the United States. Adding additional criteria for these claims, as suggested by the commenters, would continue to mislead consumers.

Comment: One domestic trade association stated that products made from offspring animals that were born, raised, and slaughtered in the United States should be eligible for ''Product of USA'' or ''Made in the USA'' claims, even if the parent animals were imported.

Response: FSIS agrees. Products made from an animal that was born, raised, slaughtered, and processed in the United States will be eligible for these claims, provided they meet any other applicable criteria. The country in which the parent animal of the animal was born, raised, slaughtered, or processed will not be relevant to a product's eligibility to bear these claims.

Comment: A few domestic and foreign trade associations and one foreign country requested clarification on whether, under the proposed criteria for ''Product of USA'' or ''Made in the USA'' claims, eggs produced in the United States from imported poultry would meet the requirement of ''born'' in the United States.

Response: Under the final rule, ''born'' in the case of a poultry species is ''hatched from the egg'' and in the case of an egg product is ''broken from the egg.'' Therefore, poultry hatched or eggs broken in the United States from either domestic or imported parents will

meet the requirement for these claims that the animal was ''born'' in the United States.

Comment: Several domestic trade associations and one foreign country opposed the proposed ''born (*i.e.,* hatched), raised, slaughtered, and processed'' requirement for use of ''Product of USA'' or ''Made in the USA'' claims on poultry products. One domestic trade association and one foreign country stated that the requirement would affect the widespread industry practice of shipping day-old chicks from Canada and other countries into the United States for the purpose of raising, slaughtering, and processing the animals to produce poultry products for the U.S. market. One domestic trade association recommended that the proposed rule allow these claims to be used on a product derived from a chicken or turkey raised from a poult shipped into the United States fewer than 48 hours after hatching, provided the animal lives the reminder of its life in the United States and is slaughtered, processed, and packaged domestically.

Response: FSIS disagrees that poultry products should be excluded from the ''born (*i.e.,* hatched)'' requirement for use of these claims. Establishing consistent requirements for the use of U.S.-origin label claims across all FSIS-regulated products will further the final rule's purpose to provide consumers with accurate label information and thus ensure labels are not misleading consumers in the marketplace. Under the final rule, establishments may choose to use an origin claim other than ''Product of USA'' or ''Made in the USA'' on the labels of poultry products to indicate the preparation and processing steps that occurred in the United States upon which the claim is made, such as ''Made from turkey slaughtered and processed in the United States'' (9 CFR 412.3(c)).

Comment: One domestic trade association stated that poultry production practices, such as the shipping of day-old chicks, were not significantly considered in developing the proposed ''born, raised, slaughtered, and processed'' criteria for voluntary ''Product of USA'' and ''Made in the USA'' label claims. The commenter noted that the RTI survey did not include examples of poultry products and that none of the petitions explained in the proposed rule asserted that consumers are confused about ''Product of USA'' label claims on poultry products.

Response: FSIS is establishing requirements for the use of voluntary U.S.-origin label claims on all FSIS-regulated products in order to maintain consistent labeling requirements for all products under the Agency's jurisdiction and to address consumer confusion about its current ''Product of USA'' labeling policy. The rule addresses the prohibition of claims that have been shown to be misleading. FSIS acknowledges that poultry products were not included in the RTI survey that support the conclusion that current claims can be misleading. However, FSIS disagrees that the findings of the RTI survey are not applicable to poultry products because they were not included as product examples in the survey questions. It would be impractical for the survey to include all product types within FSIS' regulatory jurisdiction. While the RTI survey only looked directly at a subset of beef and pork products, there is no reason to conclude that the product claims examined in that study were any less misleading when applied to chicken than they are when applied to beef. Finally, FSIS notes that the proposed rule clearly stated that these criteria would apply to poultry products (88 FR 15290). FSIS received over 1,000 comments from consumers who specifically supported the inclusion of poultry products in the proposed rule, demonstrating the need to provide consistent regulatory definitions of voluntary U.S.-origin claims for all products, including poultry products, under FSIS mandatory inspection and voluntary inspection services.

B. U.S.-Origin Claims Other Than ''Product of USA'' and ''Made in the USA''

Comment: Several domestic trade associations opposed the proposed criteria for FSIS-regulated products to be eligible to bear U.S.-origin claims other than ''Product of USA'' or ''Made in the USA,'' stating that the criteria would be too complex for industry to use the claims.

Response: FSIS disagrees that the criteria for U.S.-origin claims other than ''Product of USA'' and ''Made in the USA'' are too complex. Official establishments and facilities that label FSIS-regulated products with these claims may choose to use the label claims but are not required to do so. The final rule allows for U.S.-origin label claims other than ''Product of USA'' or ''Made in the USA,'' provided that the label claims include a description to indicate which preparation and processing steps occurred in the United States (9 CFR 412.3(c)). This description will provide consumers meaningful information about the U.S.-origin components of the product's preparation and processing. Currently, these types of voluntary U.S.-origin label claims are used on FSIS-regulated products in the U.S. retail market, which shows that they are not too complex for interested official establishments and facilities. FSIS has updated its generic labeling guidance to provide specific examples of descriptions that will provide meaningful consumer information (*e.g.,* the specific description ''Sliced and Packaged in the United States,'' rather than the generalized descriptions ''Processed in the United States'' or ''Manufactured in the United States''). The updated guidance is available on the FSIS website at: *https://www.fsis.usda.gov/guidelines/2024-0001.*

Comment: One consumer advocacy organization stated that label claims other than ''Product of USA'' or ''Made in the USA'' on products derived from animals not born in the United States would undermine the purpose of the proposed rule to provide consumers accurate information about the origin of FSIS-regulated products. To mitigate this risk, the commenter stated that FSIS should establish comprehensive requirements for these label claims that concern all label components, such as wording, placement, size, color, and readability, which could cause the consumer to be confused or uncertain concerning whether a product originated from an animal born, raised, slaughtered, and processed in the United States.

Response: The provisions for all voluntary label claims under this rule will ensure that labels of FSIS-regulated products do not mislead or confuse consumers about the origin of the product. First, as with all labeling of FSIS-regulated products, U.S.-origin claims other than ''Product of USA'' or ''Made in the USA'' must be truthful and not misleading. These other U.S.-origin label claims also will include a description of which preparation and processing steps occurred in the United States (88 FR 15290, 15306). Further, labels bearing the claims under this rule will be subject to routine FSIS Inspection Program Personnel (IPP) verification activities at establishments and facilities to verify that the generically approved labels are truthful and not misleading and comply with labeling requirements, including font size, placement, and other wording requirements under 9 CFR 317.2, 381.116, and 590.411.

Comment: A few domestic trade associations stated that the proposed requirement for voluntary U.S.-origin claims other than ''Product of USA'' and

''Made in the USA'' to include a ''description on the package'' of how the product compares to the regulatory criteria for the ''Product of USA'' and ''Made in the USA'' claims should apply only to retail labels. One commenter asked the Agency to clarify its definition of ''package'' for the purposes of this U.S.-origin label claim requirement.

Response: The description requirement for the use of voluntary U.S.-origin label claims other than ''Product of USA'' and ''Made in the USA'' will apply to the ''immediate container'' (*i.e.,* the package seen by the end user; see 9 CFR 317.1(a), 381.1, and 590.5). For clarity, FSIS has made an editorial revision to the proposed regulatory text in 9 CFR 412.3(c) to remove the ''package'' reference and to more simply state that these other voluntary U.S.-origin claims must include a description of the preparation and processing steps that occurred in the United States upon which the claim is being made.

Comment: One domestic trade association stated that products bearing U.S.-origin label claims other than ''Product of USA'' and ''Made in the USA'' should be required to include a description specifying the countries where the same production steps included in ''Product of USA'' or ''Made in the USA'' claim criteria occurred (*i.e.,* where the animal from which the product was derived was born, raised, slaughtered, and processed). The commenter also stated that all U.S.-origin label claims other than ''Product of USA'' and ''Made in the USA'' should indicate the country of origin of the product itself, not the country in which ancillary preparation or processing steps occurred. The commenter stated that preparation and processing, such as slicing and packaging, are not actual ''components'' of products. Rather, they are only features or applications applied to the products.

Response: FSIS disagrees that products bearing U.S.-origin label claims other than ''Product of USA'' and ''Made in the USA'' should be required to specify all the countries in which the originating animal was born, raised, slaughtered, and processed. The final rule will require that these U.S.-origin label claims on FSIS-regulated products include a description of the preparation and processing steps that occurred in the United States upon which the claim is made. Such preparation and processing steps may include ''born,'' ''raised,'' or ''slaughtered.'' However, they may also include other steps, such as ''sliced'' or ''packaged.'' This description requirement will ensure that consumers are provided meaningful, accurate information about the U.S.-origin of the product or of the product's preparation and processing. However, FSIS is not requiring that other country of origin information be included on the product. FSIS notes that some products under FSIS mandatory inspection or receiving voluntary inspection services may need to meet AMS COOL requirements at retail.

Comment: A few trade associations asked whether, under the proposed rule, the Agency would retain the foreign country-origin designation of imported meat products on U.S.-origin claims other than ''Product of USA'' or ''Made in the USA'' by requiring the label display of the actual country from which the imported beef was sourced, not only a generic reference to ''Imported.''

Response: As explained in the proposed rule, currently, when meat, poultry, and egg products imported into the U.S. are repackaged or otherwise processed in a FSIS-inspected facility, they are deemed and treated as domestic product for both mandatory and voluntary labeling purposes (21 U.S.C. 620 and 466, 88 FR 15290 and 15292). Under the final rule, while imported products cannot bear a ''Product of USA'' or ''Made in the USA'' label claim, official establishments and facilities will have the option to use another claim (qualified claim). The final rule will not change the requirement under the regulations that the immediate container of imported meat, poultry, and egg products must bear the name of the country of origin, preceded by the words ''Product of'' (9 CFR 327.14, 381.205, and 590.950). Further, products imported to the United States that are misbranded will continue to be eligible to be relabeled with an approved label under the supervision of FSIS personnel (9 CFR 327.13(a)(4), 381.129(b)(6)(iv)(A), and 590.956).

C. Multi-Ingredient Products

Comment: A few domestic trade associations stated that multi-ingredient products should be excluded from the scope of products subject to the proposed rule. One commenter specifically stated that FSIS failed to consult with the U.S. Food and Drug Administration (FDA) on the proposed rule and that the proposed requirements would likely lead to confusion regarding multi-ingredient products with ''Product of USA'' or ''Made in the USA'' claims, as consumers would assume all food products are held to the same standard for the label claim.

Additionally, a few domestic and foreign trade associations and one foreign country opposed the proposed criterion for multi-ingredient products bearing a ''Product of USA'' or ''Made in the USA'' label claim that all additional ingredients, other than spices and flavorings, are of domestic origin. One domestic trade association argued that the proposed ''domestic origin'' criterion for ''all other ingredients'' would cause companies seeking to use these claims on multi-ingredient products to source domestic ingredients even if the price is uncompetitive, resulting in increased cost for industry, and increased prices for consumers. The foreign country noted that the scope of the RTI survey did not include multi-ingredient products. Therefore, the commenter argued, it is uncertain whether consumers expect virtually all ingredients in a multi-ingredient product bearing a ''Product of USA'' label claim to be of U.S. origin.

Response: FSIS disagrees that multi-ingredient products should be excluded from the scope of the final rule. Under the Agency's authorizing statutes, multi-ingredient products containing meat, poultry, and egg products are within FSIS' jurisdiction and by statute, FSIS is required to ensure that such products are safe, wholesome, and properly labeled and packaged (21 U.S.C. 601 *et seq.,* 21 U.S.C. 451 *et seq.,* and 21 U.S.C. 1031 *et seq.*) FSIS is defining the conditions under which both single ingredient and multi-ingredient products may bear voluntary U.S.-origin claims to maintain consistent labeling requirements across all FSIS-regulated products. As explained in the proposed rule, this consistency will benefit consumers by aligning the meaning of U.S.-origin label claims with consumer expectations. Consumers also provided comments in support of the changes in the proposed rule (88 FR 15290, 15291). Additionally, the fact that FSIS received over 3,000 comments from other consumers who generally supported the proposed rule further demonstrates the need to provide consistent regulatory definitions of voluntary U.S.-origin claims for all products under FSIS mandatory inspection and voluntary inspection services.

FSIS also disagrees that the Agency should establish alternative criteria for the use of voluntary ''Product of USA'' and ''Made in the USA'' label claims on multi-ingredient products. The requirement that all additional (*i.e.,* not under FSIS mandatory inspection or voluntary inspection services) ingredients other than spices and flavorings must be of domestic origin will ensure that the labels do not mislead or confuse consumers about the origin of the products. This ''virtually

all'' domestic origin ingredients requirement aligns with the 2021 U.S. Federal Trade Commission (FTC) final rule related to ''Made in USA'' and similar U.S.-origin label claims (86 FR 37022, July 14, 2021). The FTC rule requires, in part, that ''all or virtually all'' of a product's ingredients or components must be made and sourced in the United States for the product to bear ''Made in the USA'' and similar claims.[13] FSIS also notes that FDA reviewed FSIS' proposed rule prior to publication as part of the standard interagency review process. While FSIS is not revising the proposed criteria for the use of voluntary ''Product of USA'' and ''Made in the USA'' label claims, the Agency has made a few minor editorial changes to the regulatory text at 9 CFR 412.3(b) to improve readability and clarity.

Further, FSIS disagrees that the findings of the RTI survey are not applicable to multi-ingredient products because they were not included as product examples in the survey questions. As noted above, it would be impractical for the survey to include all product types within FSIS' regulatory jurisdiction. As also noted above, one goal of the survey was to understand the ranking of consumer preferences for label claims, and this information is relevant to all FSIS-regulated products.

Finally, regarding one commenter's concern about costs associated with the domestic sourcing requirements for ''Product of USA'' and ''Made in the USA'' label claims on multi-ingredient products, FSIS notes that the U.S.-origin label claims covered by the final rule are voluntary. Official establishments and facilities can choose to use another U.S.-origin label claim (qualified claim), or no claim, should they decide that meeting the requirements for the ''Product of USA'' and ''Made in the USA'' claims is not desirable or cost effective for a particular multi-ingredient product.

Comment: A few domestic trade associations specifically stated that FSIS should expand the proposed ''spices and flavorings'' exception to the domestic sourcing requirement for multi-ingredient products bearing ''Product of USA'' or ''Made in the USA'' label claims. However, the commenters did not provide consistent suggestions for an alternative exception. One commenter stated that FSIS should expand the exception to other minor ingredients that do not materially affect whether consumers expect the product to be of U.S. origin. One commenter stated that the domestic sourcing requirement should apply only to major characterizing ingredients. One commenter asked whether the Agency would exempt enzymes from the domestic sourcing requirement. One commenter stated that any ingredients added for technical or functional reasons should be excluded from the domestic sourcing requirement. One commenter stated that only a majority of non-FSIS regulated ingredients should be required to be domestically sourced. Finally, one commenter stated that certain ingredients, such as phosphates, may not be considered ''spices or flavorings'' but are used in very small amounts, are necessary for food safety and functionality, and would be overly burdensome to include in the domestic sourcing requirement.

Response: FSIS disagrees that the ''spices and flavorings'' exception should be expanded for multi-ingredient products that bear voluntary ''Product of USA'' or ''Made in the USA'' claims. As stated above, FSIS is taking this regulatory action to address consumer confusion about the Agency's current ''Product of USA'' labeling policy. FSIS' review of the policy has shown that the current ''Product of USA'' label claim is misleading to a majority of consumers because consumers believe the ''Product of USA'' claim means the product was made from animals born, raised, and slaughtered, and the meat, poultry, or egg product then processed, in the United States. Also as stated above, several consumer comments indicated belief that the ''Product of USA'' label should cover requirements on multi-ingredient products and without those requirements the label would remain misleading. Furthermore, the majority of commenters have supported the proposed rule overall, which includes support for the proposed criteria for multi-ingredient U.S. origin labels. Therefore, FSIS has determined the limited ''spices and flavorings'' exception for multi-ingredient products bearing ''Product of USA'' or ''Made in the USA'' labels will provide consumers clear, accurate information.

D. Trade Concerns

Comment: Several foreign countries and foreign and domestic trade associations stated that the proposed rule would disrupt market integration between U.S. border states and Mexico or Canada.

One foreign country and one foreign trade association stated that both U.S. and foreign livestock sectors would be detrimentally affected by the proposed rule, similar to the effects that were seen as a result of mandatory AMS COOL requirements. The commenters stated that the proposed rule could lead to shifting existing supply chains away from Canadian inputs. The foreign country further stated that the proposed rule would substantially harm small and medium sized processors in U.S. border states that either regularly or in emergencies rely on Canadian imports. The foreign country argued the U.S. border states would now need to rely upon U.S. products and animal flows farther away than closer Canadian ones. The foreign country stated that by disrupting the integrated supply chain, the proposed rule did not support shared sustainability or food security goals. The foreign country stated that the proposed rule did not adequately explore alternative options and noted that alternative options are available to support improved accuracy for consumers but without posing a risk to U.S.-Canada supply chains.

Another foreign country stated that the proposed rule would disadvantage Mexican industry because U.S. meat products derived from imported Mexican cattle would no longer be eligible for ''Product of USA'' labeling, even if the cattle had spent most of their lives in the United States. The commenter stated that this would affect the export of live cattle to the United States. The foreign country stated that this disruption would include not only cattle and actual meat products, but also the grain Mexican ranchers import to feed cattle. The commenter alleged that the claims other than ''Product of USA'' and ''Made in the USA'' available for product derived from imported Mexican cattle require detailed description of the product, which would impose additional costs and could have an impact on the conditions of competition of similar Mexican products with respect to U.S. products. The foreign country stated that once a major stakeholder adopts the voluntary label claim in its operational strategy, other stakeholders will be compelled by commercial-retail dynamics to follow suit, making the labeling ''de facto'' mandatory.

Response: The final rule does not establish any mandatory country of origin labeling requirements. Producers are not required to make these claims. If certain products no longer qualify for a ''Product of USA'' or ''Made in the USA'' claim, producers can choose to use other U.S.-origin claims or not to

[13] The FTC final rule does not apply to FSIS-regulated products. In the final rule preamble, the FTC noted FSIS' authority to regulate labels on meat products sold at retail pursuant to the FMIA, as well as the Agency's plans to initiate rulemaking to address potential marketplace confusion concerning products of purported U.S. origin (86 FR 37022, 37029).

make any type of U.S.-origin claim. Therefore, analogies to AMS' mandatory COOL requirements and its alleged economic effects are inapposite. In addition, the rule does not affect or cover animal feed requirements.

To address concerns on the impact to small businesses including processors, FSIS updated the Regulatory Flexibility Act Assessment with an analysis comparing the final rule's estimated cost for small businesses using U.S.-origin claims to the average revenue for small businesses in the industry. FSIS estimates that the final rule will not have a significant economic impact on small businesses. The final rule's estimated cost per small business represents 0.005 percent to 0.01 percent of a small business' average revenue (please see the Regulatory Flexibility Act Assessment section).

FSIS also notes that, as stated above, the Agency reviewed alternative criteria for the voluntary U.S.-origin claims, which led FSIS to propose the various options for label claims other than ''Product of USA'' and ''Made in the USA'' on single ingredient and multi-ingredient products. These other options allow for various claims regarding the U.S. origin of FSIS-regulated products.

Furthermore, notwithstanding that the U.S.-origin claims will be voluntary, any assertion about the market impact of the final rule or that ''Product of USA'' or ''Made in the USA'' claims will become *de facto* commercially mandatory is speculative. As explained in the proposed rule, the Agency's research on meat, poultry, and egg product labels in the U.S. retail market as of July 2022 found that approximately 12 percent included a U.S.-origin claim (88 FR 15290, 15298).[14] Therefore, as the significant majority of FSIS-regulated products currently do not bear U.S.-origin label claims, the market effects of the final rule's voluntary labeling requirements are not expected to have a significant impact.

Comment: Several domestic trade associations that supported the proposed rule stated that FSIS should ensure that any final regulatory requirements are consistent with international trade agreements, such as the World Trade Organization (WTO) obligations and agreements among the United States, Canada, and Mexico. A few of these commenters stated that the Agency should avoid any potential resulting trade retaliation risk from trading partners.

Several foreign countries and foreign and domestic trade associations that opposed the proposed rule stated similar concerns about potential retaliatory tariffs by Canada and Mexico. A few of these commenters stated that the similarity of the proposed rule to the mandatory COOL requirements would pose too great a risk for retaliatory actions. One domestic trade association argued that resulting retaliatory actions could be worse than those under mandatory COOL because of the greater number of industries and meat products affected.

Several foreign countries and domestic and foreign trade associations specifically stated that the proposed rule could be considered a technical barrier to trade. A few of these commenters further stated that the proposed rule could lead to discrimination against imported production, inconsistent with the United States' obligations under the WTO Technical Barriers to Trade Agreement (TBT) and the United States-Mexico-Canada Agreement (USMCA) Chapter 11 on TBT, as well as Article III:4 of the General Agreement on Tariffs and Trade (GATT). One foreign country noted the proposed rule could be more trade-restrictive than necessary.

Response: The final rule is consistent with the United States' trade obligations. As FSIS has explained above and in the proposed rule, the ''born, raised, slaughtered, and processed'' requirement for the use of the claims ''Product of USA'' and ''Made in the USA'' will ensure such labels convey accurate U.S.-origin information and prevent consumer confusion in the marketplace (88 FR 15290, 15301). Unlike mandatory COOL, the ''Product of USA'' and ''Made in the USA'' label claims in this final rule are voluntary. Additionally, this final rule provides establishments with the option to make U.S.-origin claims other than ''Product of USA'' or ''Made in the USA'' (qualified claims). Imported products are not subject to less favorable treatment than domestic products under the final rule. All FSIS-regulated domestic products will be subject to the same requirement that labels must be truthful and not false or misleading, consistent with U.S. statutes and FSIS regulations.

Comment: One foreign country stated that the proposed rule would affect the tariff schedule regarding certain animals or products imported to the U.S. market. The commenter stated that the transformation that occurs from live cattle to a beef product clearly fulfills the definition of the United States International Trade Administration regarding ''substantial transformation'' to determine the origin of a good. The commenter stated that, therefore, in the case of Mexican cattle imported by the United States, the transformation includes a clear tariff shift. The commenter further noted that, for countries with which the United States has Free Trade Areas (FTAs), there is a transformation of the origin of the good based upon the FTA. Finally, the commenter stated that the proposed rule has the potential to affect ongoing regional and international efforts including, among others, equivalency recognition, mitigation and eradication of pests and diseases, and regulation harmonization.

Response: The commenter's concerns regarding tariff schedules are outside the scope of this regulatory action. This final rule establishes requirements for the voluntary labeling of FSIS-regulated products bearing U.S.-origin claims. Issues related to rules of origin under other regulatory standards or international agreements are not applicable. Furthermore, the commenter's concern about potential effects on regional and international efforts is speculative. All FSIS-regulated domestic products will be subject to the same requirement that labels must be truthful and not false or misleading, consistent with U.S. statutes and FSIS regulations.

Comment: One foreign country requested that FSIS pause and reconsider the proposed rule to allow for consultations between officials from the United States and the foreign country to ensure fulsome technical exchange on the rule, and its implications.

Response: FSIS undertook a transparent and robust proposed rulemaking process, and FSIS considered comments from all interested parties, including trading partners.

E. Exported Products

Comment: A few domestic trade associations asked FSIS to clarify that exported products would be exempt from the requirements of the proposed rule. One commenter requested clarification on whether companies would still be eligible to export beef, should they choose not to use a voluntary U.S.-origin label claim. The commenter also requested clarification on whether implementation of the proposed rule would require the

[14] As explained in the proposed rule, the analysis identified two types of U.S.-origin claims: (1) Authorized claims, *i.e.,* ''Product of USA'' or ''Made in the USA''; and (2) Qualified claims, *e.g.,* ''Raised and Slaughtered in the USA.'' Some of these labels with claims described above are also subject to COOL regulations regarding mandatory labeling depending on the commodity type (88 FR 15290, 15298).

creation of new export verification programs.

Response: As explained in the proposed rule, the regulatory requirements for voluntary U.S.-origin label claims will not apply to products intended for export from the United States (88 FR 15290). 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.[15] FSIS will continue to conduct export certification activities for FSIS-regulated products intended for export to foreign countries.[16] During this process, IPP verify that such products meet country-specific requirements, including labeling requirements, that have been officially communicated to FSIS by the importing country. Therefore, no new export verification programs are necessary under this final rule.

Comment: Several domestic and foreign trade associations, foreign countries, and a private company argued that the proposed rule would act as a mandatory rule regarding exported products, as it would require segregation of finished products from imported animals. The commenters stated that this required segregation could lead to a future WTO case against the U.S. and potential retaliation from Canada and Mexico. One domestic trade association noted that such segregation requirements were both costly and the basis of WTO findings against the United States in previous trade disagreements. Finally, one domestic trade association stated that, due to the purportedly de facto mandatory segregation requirements, smaller producers would be denied the ability to use the voluntary ''Product of USA'' or ''Made in the USA'' U.S.-origin label claims.

Response: FSIS disagrees that the final rule will establish any mandatory regulatory requirements or impose mandatory costs on industry. Under the final rule, official establishments and facilities will not be required to include a ''Product of USA'' or ''Made in the USA'' claim on the labels of FSIS-regulated products. Official establishments and facilities may also choose to use a U.S.-origin label claim other than ''Product of USA'' or ''Made in the USA,'' should they decide that meeting the requirements for a ''Product of USA'' or ''Made in the USA'' claim is not desirable or cost effective for a particular product. FSIS notes that the final rule does not require segregation of products from animals. Any costs associated with maintaining compliance with the final rule will be voluntary and incurred by official establishments and facilities that choose to use U.S.-origin label claims.

Comment: One domestic trade association asked FSIS to consider a process for returned exported product or product that must be rerouted to domestic locations before being exported that may have ''Product of USA'' labeling export requirements, so that the product can be sold domestically.

Response: As with all FSIS-regulated products, returned exported product or product that must be rerouted to domestic locations that bears a ''Product of USA'' label claim will need to meet all applicable FSIS requirements before being sold domestically. For example, an establishment may need to use a pressure sticker to correct the label.[17]

F. ''Egg Products'' Definition

Comment: One domestic trade association, one foreign trade association, and one foreign country requested clarification on the definition of the term ''egg products'' for the purpose of the proposed rule, and a few of the commenters also asked whether table eggs would be subject to the proposed rule.

Response: The regulatory requirements for egg products bearing voluntary U.S.-origin label claims will apply to ''egg products'' as defined by the EPIA (21 U.S.C. 1031 *et seq.*) and the FSIS egg products inspection regulations (See 9 CFR part 590). Under the EPIA at 21 U.S.C. 1033(f), the term ''egg product'' means any ''dried, frozen, or liquid eggs, with or without added ingredients, excepting products which contain eggs only in a relatively small proportion or historically have not been, in the judgment of the Secretary, considered by consumers as products of the egg food industry, and which may be exempted by the Secretary under such conditions as he may prescribe to assure that the egg ingredients are not adulterated and such products are not represented as egg products.'' Table eggs are not FSIS-regulated products. Therefore, under the final rule, table eggs will not be subject to the regulatory requirements.

G. RTI Consumer Survey

Comment: One domestic trade association stated that the RTI survey suggested that the proposed rule would not effectively educate consumers about the country of origin of meat or processed products. The commenter stated that the survey findings suggested that even if the proposed rule were adopted and the ''Product of USA'' label were used only on product derived from animals born in the United States, more than 50 percent of U.S. consumers still would not know the meaning of the label. The commenter also noted that only about 31 percent of the survey participants noticed the ''Product of USA'' label. Therefore, the commenter concluded, it is unlikely the rule would resolve consumer confusion about current voluntary U.S.-origin label claims.

Response: FSIS disagrees with the commenter's categorization of what the survey results showed about consumers' understanding of voluntary U.S.-origin label claims. Only 16 percent of participants understood that current ''Product of USA'' label claims meant the product was processed in the United States. In contrast, about 56 percent of the participants believed that the ''Product of USA'' label meant that the animal was at least raised and slaughtered, and the meat then processed, in the United States. Of these participants, 47 percent also believed that the ''Product of USA'' claim indicates that the animal must also be born in the United States. Together, these results suggest that the current ''Product of USA'' label claim is misleading to most consumers, and consumers believe the ''Product of USA'' claim means the product was derived from animals born, raised, and slaughtered, and the meat then processed, in the United States.

FSIS further notes, as stated above, that this ''born, raised, processed, and slaughtered'' standard for the voluntary labeling of FSIS-regulated products with ''Product of USA'' and ''Made in the USA'' claims aligns with the 2021 FTC ''Made in the USA'' final rule that requires, in part, ''all or virtually all'' of a product's ingredients or components to be made and sourced in the United States for the product to bear ''Made in the USA'' and similar label claims (86 FR 37022). Finally, as also stated above, the fact that the Agency received over 3,000 comments from consumers who generally supported the proposed rule further demonstrates the need to provide consistent regulatory definitions of voluntary U.S.-origin

[15] FSIS Export Library, available at: *https://www.fsis.usda.gov/inspection/import-export/import-export-library.*

[16] See FSIS *Directive 9000.1, rev. 2, Export Certification* (August 1, 2018), available at: *https://www.fsis.usda.gov/policy/fsis-directives/9000.1.*

[17] See FSIS *Directive 7221.1, Rev. 3, Prior Label Approval* (January 18, 2023), available at: *https://www.fsis.usda.gov/sites/default/files/media_file/documents/7221.1.pdf.*

labels claims for FSIS-regulated products.

Comment: One domestic trade association stated that the survey results did not convincingly demonstrate that marketing labels, such as ''Product of USA'' labels, are meaningfully recognized by consumers. The commenter noted that the survey results indicated most consumers were not aware of the U.S.-origin label unless prompted. The commenter stated that, contrary to the Agency's conclusion in the proposed rule, the survey did not indicate that consumers frequently noticed the ''Product of USA'' label, simply that it was noticed.

Response: FSIS disagrees that the survey failed to show that consumers frequently notice the ''Product of USA'' claim. The results from the survey showed that ''Product of USA'' label claims are noticeable and important to consumers. Results from the survey's aided recognition [18] questions showed that 70 to 80 percent of eligible consumers correctly recalled seeing the ''Product of USA'' label claim. Results from the aided recognition questions also showed that participants correctly recalled the ''Product of USA'' label claim more often than other claims. Results from the survey's unaided recall questions showed that about 1 in 3 eligible consumers reported seeing a ''Product of USA'' claim when it was accompanied by a U.S. flag icon, while about 1 in 10 eligible consumers reported seeing a ''Product of USA'' claim when it was in plain text included in a list of other claims. RTI measured participants' awareness of ''Product of USA'' claims, by their ability to accurately recall if a claim was shown. This measurement served as an indicator of their attention towards the claim. The results of both the aided and unaided tasks showed that the presence of a ''Product of USA'' claim in any form increased the participants' attention to the product, suggesting that such claims are recognizable and important to the participants.

Comment: One domestic trade association disagreed with FSIS' conclusion, based on the survey, that consumers may be willing to pay more for products with a voluntary ''Product of USA'' or ''Made in the USA'' label claim. The commenter asserted that consumer research consistently demonstrates that, while consumers may state that they are interested or willing to pay more for certain claims or characteristics, price is the most important factor when making actual purchasing decisions.

Response: The Agency acknowledges that some of the marginal wiliness to pay (MWTP) estimates are likely higher than price premiums observed in the market. However, the Agency maintains that the RTI survey correctly concluded that some consumers may be willing to pay more for products with a ''Product of USA'' claim. This is supported by similar values found in the peer-reviewed literature [19] and demonstrated by the hedonic price model explained in the rule. However, for the purposes of this rulemaking, the goal of the survey was to understand how consumers perceive the definition of the ''Product of USA'' label and the ranking of consumer preferences for labels. FSIS acknowledges that consumers consider U.S.-origin claims along with many other characteristics while purchasing products. FSIS also agrees that price is a primary factor affecting consumer purchasing decisions. For this reason, RTI randomized the price attribute in the Discrete Choice Experiment (DCE) to more accurately estimate the MWTP for the ''Product of USA'' label. While price is an important factor, so too are ''Product of USA'' claims. The results from the RTI survey show that ''Product of USA'' claims are noticeable and important to consumers. Results from the survey's aided recognition questions show that 70 to 80 percent of eligible consumers correctly recalled seeing the ''Product of USA'' claim (88 FR 15290, 15294). The ''Product of USA'' requirements are intended to reduce false or misleading U.S.-origin labeling. This will reduce the market failures associated with incorrect and imperfect information. The changes will benefit consumers by aligning the voluntary ''Product of USA'' and ''Made in the USA'' label claims with the definition that consumers' likely expect, *i.e.,* as product being derived from animals born, raised, slaughtered, and processed in the United States.

Comment: One foreign trade association raised several concerns related to the RTI study methodology, as well as the analysis and purported accuracy of its findings. The commenter also included information about a separate consumer survey that the commenter commissioned to inform their comments on the proposed rule. The separate consumer survey showed that consumers have a MWTP premium for the ''Product of USA'' claim over the base product price. However, the separate consumer survey estimated MWTP values that were less than the estimated MWTP values in the RTI survey. The commenter concluded that a new research approach is needed before FSIS can determine the benefits and costs of changing the Agency's policy on use of the ''Product of USA'' label claim.

Response: FSIS notes that a few of the commenter's stated concerns about the RTI survey methodology were, in fact, editorial in nature. The Agency has reviewed these editorial comments and determined that they do not affect the results of the RTI survey or provide substantive information that the Agency could use to inform rulemaking. FSIS' responses to the commenter's other, non-editorial concerns follow:

Comment: The commenter noted that in an unaided consumer survey recall question, a very small proportion of participants recalled the ''Product of USA'' label on the package of ground beef they viewed, even though they were given 20 seconds to look at just one image, and even when ''Product of USA'' was next to a U.S. flag on the package. The commenter also argued that RTI did not provide a rationale for the consumer recall time of 20 seconds to notice the ''Product of USA'' label.

Response: FSIS disagrees that the survey results suggested a lack of consumer notice and importance of the ''Product of USA'' label. FSIS recognizes the limitations of the limited time exposure (LTE) experiment used during the survey, in that the survey is not a real-world setting. Given the nature of the experiment, RTI was only able to test recall when the ''Product of USA'' label was shown on the front of the package. RTI demonstrated that recall of ''Product of USA'' claims were statistically significant using the test of independent proportions. The 20-second time period was chosen based on input from an RTI expert in the LTE approach and data collected during an FSIS survey on safe handling

[18] For the limited time exposure portion of the RTI survey, participants were randomly assigned to view one of four mock products that varied in terms of whether the ''Product of USA'' claim was present and, if present, the location and format of the ''Product of USA'' claim. Participants were asked to list what labeling features they recalled. This first set of questions were considered unaided because they did not ask if the participant recalled seeing a specific image or phrase, and responses were open-ended. Participants then answered a set of questions to indicate whether they saw specific images and phrases (including the ''Product of USA'' claim). This second set of questions were considered aided because they asked the participant if they recalled seeing a specific image or phrase, and responses were closed ended (yes/no).

[19] (1) Loureiro, M.L., & Umberger, W.J. (2007). A choice experiment model for beef: What US consumer responses tell us about relative preferences for food safety, country-of-origin labeling and traceability. Food policy, 32(4), 496–514. (2) Lusk, J.L., Schroeder, T.C., & Tonsor, G.T. (2014). Distinguishing beliefs from preferences in food choice. European Review of Agricultural Economics, 41(4), 627–655.

instructions pretesting. Further, FSIS notes that when participants were directly asked during the survey whether they look for the ''Product of USA'' label when shopping for ground beef, 45 percent of eligible consumers responded ''most of the time'' or ''always'' and 25 percent responded ''sometimes.'' These results provided additional evidence that consumers rely on the ''Product of USA'' label when making purchase decisions.

Comment: The commenter stated that the MWTP for the ''Product of USA'' label resulting from the DCE models was too high compared to the price.

Response: FSIS disagrees. The commenter incorrectly summed the MWTP from two different DCE models described in the survey, $1.69 in DCE1 and $1.15 in DCE2 for ground beef. These models were two different discrete choice experiments with different respondent groups and measured two different preferences. Therefore, the results of each experiment were independent from one another, and the results should not be summed.

Further, the individual MWTP values are similar to those found in the peer-reviewed literature. Ideally, FSIS would compare estimates to other studies that investigate the MWTP for the ''Product of USA'' label. However, such a direct comparison is not possible given that no previous study has investigated the MWTP for products with this specific label. But, estimates obtained from other DCEs from the literature could be informative. For example, in a hypothetical choice experiment, Loureiro & Umberger [20] found that the average U.S. respondent in their study was willing to pay $2.57 (2003 dollars) per pound more for a ribeye steak that featured a country of origin label over an otherwise identical steak that did not feature a country of origin label. Alternatively, in a non-hypothetical choice experiment, Lusk et al.[21] found that U.S. consumers in their sample were willing to pay $1.68 more for a 12 oz. beef steak that was of United States origin than an otherwise identical ''weighted average origin'' steak. Although neither of these estimates are directly comparable to the MWTPs estimated in the RTI survey, they illustrate that the estimated MWTPs are not excessively high.

The Agency acknowledges that some of the estimated MWTP are likely higher than real world price premiums. This is demonstrated by the hedonic price model explained in the rule. This difference is likely because the estimated MWTP rely on stated preferences and may not reflect actual purchasing preferences in real life situations, as the survey respondents do not have their own money on the line. However, FSIS notes that, as explained in the proposed rule, the Agency did not rely on the MWTP results when calculating costs and benefits (88 FR 15290, 15302). Rather, FSIS used the ranking of preferences to inform its rulemaking.

Comment: The commenter argued that there were inaccuracies in the survey report description of the random utility models and mixed logit models that RTI used to test the hypotheses and estimate the MWTP. The commenter argued that the purported inaccuracies undermine confidence in the DCE survey results.

Response: FSIS disagrees that the RTI report description contains inaccuracies. Rather, the report description accurately explains: (1) that utility is composed of observable and unobservable components (Equation 2.1), (2) that the likelihood a person will choose one product over another depends on differences in utility of the two products (Equation 2.2), and (3) that observable utility is a linear function of product attributes (Equations 2.3 and 2.4). FSIS notes that these equations are all presented before mixed logit modeling is introduced. Therefore, these equations are accurate. Further, Equations 2.1 and 2.2 have been used in a peer-reviewed publication that used mixed logit modeling and was co-authored by RTI research personnel.[22] In addition, RTI's use of the mixed logit model enhances the standard approach of using conditional logit models in discrete choice experiments. The mixed logit model allows greater flexibility through relaxed assumption and extends the standard conditional logit model by allowing one or more of the parameters in the model to be randomly distributed.[23]

Comment: The commenter stated that RTI failed to provide reasoning for excluding one-third of DCE1 participants from its analysis.

Response: Explanations as to why RTI excluded participants from the analysis are provided in the final report; section 2.4 specifically details why RTI correctly excluded participants that participated in the soft launch from the DCE analyses.[24] These participants were excluded because the soft launch survey did not ask if the respondents had purchased the assigned DCE product within the past 6 months. The relevance of this question was revealed after RTI analyzed the results of the soft launch and added the question to the final survey. Excluding the soft launch participants ensured the survey results were based on the intended survey population.[25] More importantly, participant population used in DCE1 was robust enough to produce statistically sufficient results.

Comment: The commenter questioned RTI's methodology for the DCEs. Specifically, the commenter disagreed with how RTI handled participants who selected ''neither'' as a choice in the two DCEs.

Response: RTI used a standard method to control for the participants who selected the ''neither'' choice. RTI accounted for the ''neither'' choice by introducing an alternative-specific constant into the utility function for the ''neither'' choice. This constant allowed RTI to track and monitor ''neither'' responses and ensure results were statistically sufficient. RTI considered this method as the most straightforward approach to address such opt-out effects.[26]

Comment: The commenter expressed concern that MWTP estimates for various attributes measured in DCE1 and DCE2 were in strong statistical contradiction with one another.

Response: The commenter's concerns are unfounded. The findings the commenter cited resulted from two different sample groups, and the differences do not invalidate the findings. Further, the commenter's concerns around attributes other than those associated with ''Product of USA'' claims are beyond the scope of the RTI

[20] Loureiro, M.L., & Umberger, W.J. (2007). A choice experiment model for beef: What US consumer responses tell us about relative preferences for food safety, country-of-origin labeling and traceability. Food policy, 32(4), 496–514.

[21] Lusk, J.L., Schroeder, T.C., & Tonsor, G.T. (2014). Distinguishing beliefs from preferences in food choice. European Review of Agricultural Economics, 41(4), 627–655.

[22] *See* Finkelstein, E.A., Mansfield, C., Wood, D., Rowe, B., Chay, J., & Ozdemir, S. (2017). *Trade-Offs Between Civil Liberties And National Security: A Discrete Choice Experiment.* Contemporary economic policy, 35(2), 292–311.

[23] Train, Kenneth E. 2009. Discrete Choice Methods with Simulation, Cambridge, England: Cambridge University Press.

[24] Cates, S. et al. 2022. Analyzing Consumers' Value of ''Product of USA'' Label Claims. Contract No. GS–00F–354CA. Order No. 123–A94–21F–0188. Prepared for Andrew Pugliese.

[25] The survey population was defined as adult consumers who do at least half of the grocery shopping in the household and had purchased the randomly assigned DCE product within the past 6 months.

[26] Campbell, D., & Erdem, S. (2019). *Including opt-out options in discrete choice experiments: issues to consider.* The Patient-Patient-Centered Outcomes Research, 12, 1–14.

survey and not relevant to the Agency's rulemaking.

Comment: The commenter argued that the RTI survey MWTP findings are generalizable only to participants who typically purchase 85 percent lean/15 percent fat ground beef, not to consumers of all product types. To support this assertion, the commenter cited results of its own commissioned survey, which the commenter argued showed the MWTP for ground beef with a ''Product of USA'' label would likely be lower for consumers who purchase higher fat ground beef, and that it is likely that the MWTP depends on the price a consumer typically pays for ground beef.

Response: FSIS agrees that a single MWTP estimate cannot be generalized across all product types. However, the RTI survey included three example products: ground beef, NY strip steak, and pork tenderloin. These example products resulted in data for two species and a range of product values. The RTI survey found that all three of these products resulted in positive MWTPs for the ''Product of USA'' claim. The resulting per pound MWTPs were $1.69 for ground beef; $1.71 for pork tenderloin; and $3.21 for NY strip steak (see table 9 in the Expected Benefit of the Final Rule section).

However, as explained in the proposed rule, the goal of the RTI survey was to understand how consumers perceive the definition of the ''Product of USA'' label and the ranking of preferences (88 FR 15290, 15301), and this ranking can be generalized to similar products. For example, if a consumer thinks that a ''Product of USA'' claim displayed on an 85 percent lean/15 percent fat ground beef product label meant that the originating animal was born, raised, processed, and slaughtered in the United States, the consumer likely would think that a ''Product of USA'' claim has the same meaning when displayed on a 90 percent lean/10 percent fat ground beef product. Further, FSIS notes possible problems with the methodology and purported findings of the commenter's commissioned study and resulting MWTP estimates. Although RTI and FSIS do not have access to the survey instrument used, the report included with the comment submission seems to indicate that respondents were simply asked how much they would pay for different meat products. Specifically, as the report notes, ''respondents were shown different versions of ground beef packages and asked how much they would pay for each version.'' If that statement is correct, this question format is known as an open-ended contingent valuation question. This question format is known to be associated with a number of problems. Specifically, these questions are difficult for respondents to answer and are not compatible with assessing purchasing incentives. These problems led to a recommendation against using this question format in the 1993 ''Report of the National Oceanic and Atmospheric Administration (NOAA) Panel on Contingent Valuation.'' [27]

Comment: The commenter stated concerns that the RTI survey results on the differences in the MWTP between the two surveyed groups was not statistically significant, because RTI used an insufficient sample size.

Response: The commenter's concerns are unfounded. The differences in MWTP between the two groups was a finding of the model, not an error. Although the sample size of one group may be slightly lower, the results show consumers are willing to pay more for more product information.

H. Cost Benefit Analysis

Comment: Several commenters, including domestic and foreign trade associations and foreign countries, stated that the estimated additional costs explained in the cost benefit analysis failed to consider several practical issues that producers would experience under the proposed rule, which they stated would be similar to issues under mandatory labeling programs. For example, a few of the commenters stated that, under the AMS mandatory COOL program, producers have been forced to limit the facilities, times, and quantities of animals to be slaughtered to segregate meat products that can be labeled as ''Product of the U.S.A.'' from those that cannot. One foreign country also cited as a possible additional de facto mandatory cost the relabeling of products in the event of supply chain disruptions.

Response: FSIS disagrees that costs associated with the AMS COOL program or other mandatory labeling programs can be used to estimate anticipated costs associated with the final rule, which will impose no mandatory costs for industry. Under the final rule, official establishments and facilities will not need to include these voluntary claims on the labels of FSIS-regulated products. Official establishments can also choose to modify existing ''Product of USA'' or ''Made in the USA'' claims as necessary, should they decide that meeting the requirements for these specific claims is not beneficial or practical for a particular product.

Comment: Several commenters stated that the Agency failed to account for likely costs associated with the proposed rule. For example, according to a few domestic and foreign trade associations and foreign countries, companies would likely need to adopt costly changes in their production, slaughter, and processing practices to segregate animals and products through the supply chain. One domestic trade association cited possible costs related to conflicting labeling requirements among the United States and importing countries. A few domestic trade associations raised concerns about possible costs specific to companies that want to label ''local'' products with State or region-origin claims and may incur costs from using longer supply chains or sourcing less commercially available domestic ingredients.

Response: As explained in the proposed rule and the final cost benefit analysis, FSIS recognizes that official establishments and facilities that choose to use U.S.-origin label claims may incur costs based on this rule (88 FR 15290, 15298). However, the final rule will also benefit consumers and producers by establishing a requirement for the ''Product of USA'' label claim that will more accurately convey U.S.-origin product information and that is aligned with consumers' understanding of that claim in the marketplace. FSIS disagrees that implementation of this final rule will cause industry to adopt costly changes in their production, slaughter, and processing practices to segregate animals and products through the supply chain. Given the likely small premiums from and between origin claims, businesses lack an incentive to require their suppliers to make these changes. The Agency's hedonic price model, as explained in the proposed rule, estimated a price premium of 2.5 percent, or 10 cents per pound, for claims exclusive to U.S. origin (88 FR 15290, 15302). The model also estimated a price premium of 4.2 percent, or 16 cents per pound, for a claim that included multi-country origin claims referring to the U.S. and other countries.

FSIS further notes that the voluntary final rule does not impose any segregation requirements for products or originating animals. As another commenter on the proposed rule stated, if an establishment thinks that compliance costs for the voluntary requirements will outweigh price premiums, it can simply decide not to

[27] Whitehead, J.C. (2006). *A practitioner's primer on the contingent valuation method.* Handbook on contingent valuation, 66–91; Arrow, K., Solow, R., Portney, P.R., Leamer, E.E., Radner, R., & Schuman, H. (1993). *Report of the NOAA panel on contingent valuation.* **Federal Register**, 58(10), 4601–4614.

use a voluntary U.S.-origin label claim. State and region-origin claims were included in the rule's cost analysis. While one commenter described the possibility of increased costs, other commenters noted that use of origin claims will increase benefits.

Comment: One trade association requested the Agency explain whether it considered how the proposed rule may impact current market access for U.S. beef exports, and how a reduction in market access may negatively affect the profitability of U.S. cattle producers. The trade association also stated concern that packers and feedlots may start discounting cattle that do not spend their entire lives in the United States.

Response: FSIS notes that, as explained in the proposed rule, the regulatory requirements for U.S.-origin label claims will not apply to products intended for export from the United States (88 FR 15290, 15291). FSIS will continue to conduct export certification activities for FSIS-regulated products intended for export to foreign countries.[28]

FSIS does not expect packers and feedlots to start discounting cattle that do not spend their entire lives in the United States given the limited price premiums associated with these voluntary claims. The Agency's hedonic price model, as explained in the proposed rule and in this final rule, estimated a price premium of 2.5 percent, or 10 cents per pound, for claims exclusive to U.S. origin (88 FR 15290, 15302). The model also estimated a price premium of 4.2 percent, or 16 cents per pound, for a claim other than ''Product of USA'' or ''Made in the USA'' that included multi-country origin claims referring to the U.S. and other countries. Based on these results, consumers value foreign-sourced products, which suggests that there is no incentive to change purchasing of foreign sourced cattle, or packers and feedlots to discount this cattle.

Comment: One domestic trade association noted that the cost benefit analysis addressed retail labeling costs, but the commenter stated that the proposed rule would affect all labels, including those along the supply chain to support retail labels.

Response: The labels with which the commenter was concerned are included in the range of labels impacted by this rule (88 FR 15290, 15298). The cost benefit analysis considered the relabeling costs associated with 88,537 to 108,211 labels that include voluntary U.S.-origin claims. The cost benefit analysis also included recordkeeping costs, which encompasses the relevant supply chain cost to support labels. Therefore, FSIS accounted for all relevant costs in the final rule.

Comment: One domestic trade association noted that the Agency assumed in the cost benefit analysis that brands with fewer than 50 Universal Product Codes (UPCs) associated with FSIS-regulated products were small businesses. The commenter stated that this was an unsupported assumption, as the number of UPCs associated with a brand does not always indicate the size of a business, and small businesses may co-pack for other brands and supply to other companies. Further, the commenter stated, large businesses may not produce many directly-branded products but may supply many other companies that use many UPCs. The commenter also stated the number of UPCs provides no indication about the volume of product sold for each UPC.

Response: FSIS acknowledges that the number of small businesses is an estimate and relies on assumptions, but in absence of better data, FSIS is using this estimate to calculate the number of small businesses that may be affected by the final rule. FSIS does not have access to proprietary data reflecting the sales volume of brands, including those with authorized or qualified label claims, to calculate business profit margins. Also, commenters did not provide FSIS with sales data leading to more refined estimates.

Comment: One domestic trade association stated that although FSIS considered the cost of relabeling, the cost benefit analysis did not evaluate the lost margin cost of no longer using the voluntary ''Product of USA'' label claim. Therefore, according to the commenter, the Agency failed to evaluate lost value for those operations that will no longer be allowed to use the claim.

Response: Under the final rule, FSIS expects those businesses whose product does not meet the requirements for the ''Product of USA'' or ''Made in the USA'' claims (authorized claims) to be able to use claims other than ''Product of USA'' or ''Made in the USA''. As explained in the proposed rule, the Agency's hedonic price model found a price premium of 2.5 percent, or 10 cents per pound, for claims exclusive to U.S. origin (88 FR 15290, 15302). The model found a higher price premium of 4.2 percent, or 16 cents per pound, for multi-country origin claims referring to the United States and other countries. These premium values demonstrate that ''Product of USA'' or ''Made in the USA'' claims and other multi-country origin claims garner similar price premiums.

I. Recordkeeping Requirements

Types of Documentation and Recordkeeping Costs

Comment: One domestic trade association stated that supporting documentation requirements should be simple, consistent with existing practices, and outlined in guidance, not regulation. The commenter also stated that the requirements should be limited to documentation that is needed to meet the standard that labels are truthful and not misleading. One other domestic trade association stated that the only documentation required for verifying a ''Product of USA'' or ''Made in the USA'' label claim for beef products should be a declaration that the live animal bore no import markings when presented for slaughter at a U.S. slaughter establishment.

Response: The final rule establishes general recordkeeping requirements that provide flexibility for official establishments and facilities that choose to use a voluntary U.S.-origin label claim on FSIS-regulated products. The new regulatory text provides examples of the types of documentation that may be maintained to support a U.S.-origin label claim. Official establishments and facilities may choose which types of documentation to maintain, based on the particular U.S.-origin claim they seek to use and other considerations relevant to the product. As explained in the proposed rule, FSIS will accept existing documentation to demonstrate compliance with one or more of the regulatory requirements, such as records an official establishment or facility already may maintain to comply with other FSIS regulations or as part of its participation in another federal program (88 FR 15290, 15296). FSIS has updated its labeling guidance on the use of voluntary U.S.-origin label claims, to provide more examples of the types of documentation that official establishments and facilities may maintain to support use of the claims. The updated guidance is available on the FSIS website at: *https://www.fsis.usda.gov/guidelines/2024-0001*.

Comment: One domestic trade association stated that the Agency should explain whether, under the proposed rule, IPP would perform verification activities on farms and feedlots. The commenter also requested clarification on the types of

[28] See FSIS *Directive 9000.1, Rev. 2, Export Certification* (August 1, 2018), available at: *https://www.fsis.usda.gov/policy/fsis-directives/9000.1*.

documentation that farms and feedlots would be required to provide to the processor to verify that supporting documentation complies with the proposed requirements.

Response: FSIS IPP will perform routine verification activities at establishments to verify that labels bearing voluntary U.S.-origin claims comply with labeling requirements. All labels that are generically approved under the FSIS regulations are subject to such establishment-based IPP verification procedures. FSIS will not perform verification activities at farms or feedlots. Establishments and facilities will need to obtain from farms and feedlots documentation that will support the recordkeeping requirements for the use of voluntary U.S.-origin claims, such as load sheets and grower records (88 FR 15290, 15297).

Comment: A few domestic and foreign trade associations asserted that the proposed recordkeeping requirements were too costly, and that the burden of recordkeeping and related compliance costs would also vary based on an operation's location, type, and size.

Response: FSIS disagrees that the recordkeeping requirements are too costly. The use of origin claims will continue to be generically approved. The Agency expects many businesses will use existing records to support origin claims. Alternatively, businesses can reduce their recordkeeping costs by adjusting the claim that they use, from a ''Product of USA'' or ''Made in the USA'' claim (authorized claim), to another U.S.-origin claim (qualified claim). As explained in the proposed rule, the Agency's hedonic price model found similar price premiums for ''Product of USA'' claims and other U.S.-origin claims (88 FR 15290, 15302).

Traceability and Confidentiality

Comment: Several domestic trade associations stated concerns about the feasibility of maintaining records that provide full traceability back to originating farms and producers. A few of these commenters also stated concerns about the potential for recordkeeping requirements to compromise confidentiality of business operations information. One commenter stated that, unlike the current voluntary USDA AMS Processed Verified Program (PVP) and Quality Assessment Programs (QSA), in which information disclosure is made to a third-party verifying agent, producers subject to the proposed regulatory requirements may be forced to more widely disclose proprietary information.

Response: FSIS disagrees that the voluntary U.S.-origin labeling requirements will impose infeasible recordkeeping requirements with regards to traceability. Establishments are already required to keep records of all labeling, both generically approved and sketch-approved by FSIS, along with the product formulation and processing procedures, as prescribed in 9 CFR 320.1(b)(11), 381.175(b)(6), and 412.1. Further, under 9 CFR 412.1(a), establishments must keep any additional documentation needed to support that the labels are consistent with FSIS regulations. Establishments choosing to use a U.S.-origin label claim on a FSIS-regulated product will be required to maintain records that provide sufficient information to support that the labels are consistent with FSIS regulations.

FSIS also disagrees that producers subject to the regulatory requirements may be forced to disclose proprietary information. FSIS protects the confidentiality of proprietary or confidential industry information to which Agency personnel are afforded privileged access while carrying out their responsibilities.[29] This information includes background information that may be provided during the label approval process or maintained as part of generic label approval requirements. As with all business records containing proprietary or confidential information that official establishments and facilities are required to maintain under FSIS labeling regulations, records maintained to meet the U.S.-origin labeling requirements will be protected from disclosure.

Third-Party Certification

Comment: In the proposed rule, FSIS requested comment on whether the Agency should allow or require third-party certification for U.S.-origin label claims. In response, several domestic trade associations stated that FSIS should not require third-party certification of U.S.-origin claims. The commenters noted that FSIS does not currently require third-party certification for most label claims, and they stated that requiring third-party certification would be overly burdensome and expensive. One commenter also noted that a possible third-party certification requirement was not evaluated in the cost benefit analysis. In contrast, a few domestic trade associations stated that FSIS should allow or require USDA verification of voluntary U.S.-origin label claims, such as through the USDA AMS PVP. These commenters stated that, without meaningful audit and verification, the potential for ambiguous and inconsistent labeling of FSIS products would continue under the proposed rule.

Response: After reviewing the comments, FSIS has decided at this time not to require third-party certification for U.S.-origin label claims. Currently, FSIS only requires third-party certification for non-GMO claims because of the complexity of those claims. Current label recordkeeping requirements and Agency verification procedures for the use of origin label claims will be sufficient to ensure compliance with requirements for these label claims. As with all label claims, establishments have the option of obtaining third-party certification of their labeling claims or participating in applicable AMS PVP programs. Under the final rule, establishments using a voluntary U.S.-origin claim on labels of FSIS-regulated products must maintain documentation sufficient to demonstrate that the product complies with regulatory requirements.

J. U.S. State, Territory, and Locality-Origin Claims

Comment: A few domestic trade associations supported the inclusion of voluntary U.S. State and region-origin claims within the scope of the proposed rule. A few other domestic trade associations opposed the inclusion of U.S. State and region-origin claims. One domestic trade association stated concern about potential labeling compliance costs for producers of State or region-origin products. One other domestic trade association stated that FSIS should undertake separate rulemaking on the issue of State and region-origin label claims.

Response: FSIS disagrees that separate rulemaking is needed to address the use of voluntary U.S. State, Territory, and locality-origin label claims on FSIS-regulated products. Courts have determined that Agencies may make changes to the final rule that are logical outgrowths of the proposed rule, and do not require a separate notice and comment period.[30] As stated above, FSIS received comments supporting the inclusion of U.S. State and region-origin claims within the scope of the proposed rule. Also as stated above, the proposed rule directly addressed requirements for U.S. State and region-origin claims, and FSIS originally proposed to clarify these

[29] See FSIS *Directive 4635.6, Safeguarding Confidential Industry Information* (March 25, 1985), available at: *https://www.fsis.usda.gov/sites/default/files/media_file/2020-08/4735.6.pdf.*

[30] *Long Island Care at Home, Ltd.* v. *Coke*, 551 U.S. 158 (2007).

requirements in Agency guidance (88 FR 15290, 15296). Further, a label claim indicating the specific U.S. State, U.S. Territory, or U.S. locality origin of a FSIS-regulated product or product component is inherently a U.S.-origin label claim. Therefore, it is appropriate, and a logical outgrowth of comments received on the proposed rule to include such claims within the scope of this final rule. This rule will align Agency labeling requirements for specific U.S. State, Territory, and locality-origin claims with the requirements for broad U.S.-origin label claims, which will further the Agency's intent to reduce consumer confusion about what the ''Product of . . .'' label means.

As explained in the proposed rule, currently, State and region-origin claims may be generically approved for use on FSIS-regulated product labels if they are not misleading and they comply with the requirement under 9 CFR 317.8(b)(1) to properly identify the State, Territory, or locality in which the product was prepared (88 FR 15290, 15296). The final rule requirements for U.S. State, territory, and locality-origin claims are consistent with the proposed rule. Under the final rule, FSIS-regulated products labeled with ''Product of . . .'' or ''Made in the . . .'' claims referring to the origin of a U.S. State, Territory, or locality will need to meet the regulatory criteria under 9 CFR 412.3(a) and (b) for these claims (*e.g.,* a single ingredient product labeled with such a claim will need to be derived from an animal born, raised, slaughtered, and processed in the State, Territory, or locality). Label claims other than ''Product of . . .'' or ''Made in the . . .'' that refer to the U.S. State, territory, or locality-origin components of a FSIS-regulated product's preparation and processing will need to meet the criteria under 412.3(c) for these claims (*i.e.,* the claims will need to include a description of the preparation and processing steps that occurred in the State, Territory, or locality upon which the claim is made.) This requirement will ensure consistent U.S.-origin labeling, which includes origin labeling for all U.S. States, Territories, and localities, for FSIS-regulated products. FSIS has revised the proposed regulatory text in 9 CFR 412.3, as well as the existing regulatory text in 9 CFR 317.8(b)(1) and 9 CFR 381.129(b)(2),[31] to clarify these requirements for voluntary label use of U.S. State, territory, and locality-origin claims.

K. U.S. Flag Imagery

Comment: A few domestic trade associations asked the Agency to clarify when display of the U.S. flag on labels of FSIS-regulated products would be considered use of a voluntary ''Product of USA,'' ''Made in the USA,'' or other U.S.-origin claim. One of the commenters asked how the Agency's policy on U.S. flag imagery would correspond to U.S. State and region-origin label claims.

Response: Under current FSIS policy, display of the U.S. flag on labels of FSIS-regulated products is considered the display of a geographic landmark claim. Under the FSIS regulations, geographic landmark label claims must comply with the requirements in 9 CFR 317.8(b)(1) and 381.129(b)(2) to properly identify the State, territory, or locality in which the product was prepared or produced. Geographic landmark label claims, including flags, are eligible for generic approval under the regulations (88 FR 2798, 2805).

Under the final rule, the voluntary display of the U.S. flag, or a U.S. State or territory flag, on FSIS-regulated products will be considered use of a voluntary origin claim of the United States or the relevant U.S. State or territory. Specifically, display of a standalone image of the U.S. flag, or a U.S. State or Territory flag, will need to meet the requirements under 9 CFR 412.3(a) and (b) for use of voluntary ''Product of . . .'' and ''Made in . . .'' claims (*e.g.,* a single-ingredient product labeled with a standalone display of the U.S. flag must be derived from an animal born, raised, slaughtered, and processed in the United States). The display of an image of the U.S. flag, or a U.S. State or territory flag, may be used to designate the domestic origin of a component of a FSIS-regulated product's preparation and processing, but the flag image will need to be accompanied by a description of the preparation and processing steps that occurred in the United States, or the relevant U.S. State or territory, upon which the claim is being made (*e.g.,* display of the New York State flag on a sausage product with the accompanying description ''Sliced and Packaged in New York''). FSIS has updated its labeling guidance on the use of voluntary U.S.-origin label claims, to provide a visual example of how the display of a U.S. flag, or a U.S. State or territory flag, may be used to designate the domestic origin of a component of a FSIS-regulated product's preparation and processing. The updated guidance is available on the FSIS website at: *https://www.fsis.usda.gov/guidelines/2024-0001*.

FSIS has revised the proposed regulatory text in 9 CFR 412.3 to clarify the requirements for the voluntary label display of the U.S. flag, or a U.S. State or territory flag, on FSIS-regulated products. FSIS has also revised the regulatory text in 9 CFR 317.8(b)(1) and 381.129(b)(2), relating to labeling that indicates a product's geographic significance or locality, to clarify the requirements for such voluntary label use of U.S., U.S. State, and U.S. territory flags. As with all labels that are generically approved under the FSIS regulations, label use of the U.S. flag and U.S. State and territory flags will be subject to routine verification activities at establishments by IPP to verify that the labels comply with labeling requirements.[32] The labels must be truthful and not misleading.

As stated above, label displays of the U.S. flag, or a U.S. State or territory flag, are inherently claims indicating a product's origin. As results from the consumer survey show, the final rule requirements for the voluntary use of the U.S. flag, or a U.S. State or territory flag, on FSIS-regulated products will ensure that the labels are consistent with consumers' understanding and expectations of products labeled with such flags. Results from the consumer survey's unaided recall questions showed that about 1 in 3 eligible consumers reported seeing a ''Product of USA'' claim when it was with a U.S. flag icon, while about 1 in 10 eligible consumers reported seeing a ''Product of USA'' claim when it was in plain text included in a list of other claims (88 FR 15290, 15301). These results suggest that consumers are interested in label displays of the U.S. flag and associate such labeling with their understanding of what the ''Product of USA'' label means.

L. Cell-Cultured Meat Products

Comment: Several animal welfare and policy organizations asked FSIS to address how, under the proposed rule, the Agency will consider FSIS-regulated cell-cultured meat and poultry products that bear voluntary U.S.-origin label claims. One commenter stated that cell-cultured products should be eligible for generic label approval when they are processed in the United States. One other commenter stated that, as a direct competitor to traditionally produced meat and poultry products, cell-cultured

[31] While the provisions in 9 CFR 317.8(b)(1) prohibit the false or misleading labeling of FSIS-regulated products generally, the FSIS regulations at 9 CFR 381.129(b)(2) also prohibit the false or misleading labeling of FSIS-regulated poultry products specifically.

[32] See FSIS *Directive 7221.1, Rev. 3, Prior Label Approval* (January 18, 2023), available at: *https://www.fsis.usda.gov/policy/fsis-directives/7221.1*.

meat and poultry products should be eligible to bear the same voluntary U.S.-origin label claims as FSIS-regulated slaughtered products, and that the process should not be more burdensome.

Response: As FSIS has explained in the advance notice of proposed rulemaking concerning these products, the labels of FSIS-regulated cell-cultured meat and poultry products are not currently eligible for generic approval under the Agency's prior label approval system (86 FR 49491, 49493, September 3, 2021). Therefore, FSIS will review all labels and claims on these products before they can be used in commerce to ensure they are truthful and not misleading. The criteria for use of voluntary U.S.-origin claims under this final rule will apply to cell-cultured product under FSIS jurisdiction. The voluntary label claims ''Product of USA'' and ''Made in the USA'' will be allowed on cell-cultured products only if all the preparation and processing steps for the cells occurred in the United States.

M. Enforcement of Regulatory Requirements

Comment: A few domestic trade associations requested FSIS clarify how the Agency intends to enforce violations of the new labeling requirements, such as when documentation is determined to be insufficient to support a voluntary U.S.-origin label claim.

Response: For enforcement of this rule, FSIS will follow existing FSIS regulations and FSIS Directives. When a label is not in compliance with the regulatory requirements, IPP are to document the noncompliance, in accordance with 9 CFR 412.1.[33] In addition, IPP are to retain any product bearing that label and require establishments to update labels that are not in compliance with FSIS' labeling regulations. Before the product may enter commerce, the establishment must take corrective actions. Further, in the case of intentional non-compliance with FSIS labeling regulations, the Agency may take action to control misbranded products and take enforcement action under the FSIS Rules of Practice (9 CFR part 500).

N. Implementation of Regulatory Requirements

Comment: A few domestic trade associations stated that industry will need sufficient time to implement the required changes under the proposed rule. One trade association supported the Agency's plan, as explained in the proposed rule, to use the predetermined uniform compliance date schedule for implementation of the regulatory requirements (88 FR 15290, 15297). One foreign country requested that, if the final rule is finalized, FSIS delay the timeline for implementation to allow producers to better prepare for the requirements.

Response: As explained in the proposed rule, FSIS generally uses a uniform compliance date for new labeling regulations (88 FR 15290, 15297). The uniform compliance date is intended to minimize the economic impact of labeling changes by providing for an orderly industry adjustment to new labeling requirements that occur between the designated dates.[34] Per the uniform compliance date schedule, establishments will need to comply with the new regulatory requirements on January 1, 2026 (87 FR 77707, December 20, 2022). On that date, FSIS will consider as compliant only labels bearing the voluntary claims ''Product of USA,'' ''Made in the USA,'' and other U.S.-origin claims for FSIS-regulated products that meet the codified requirements for the use of such claims. Establishments may choose to voluntarily change their labels to comply with the final rule before January 1, 2026. This compliance date will provide sufficient time to implement the voluntary labeling requirements for official establishments and facilities that choose to include U.S.-origin claims on labels of FSIS-regulated products.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.) 12866 (as amended by E.O. 14094) and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been reviewed by the Office of Management and Budget under E.O. 12866 although it has not been designated a ''significant'' regulatory action by the Office of Information and Regulatory Affairs under section 3(f)(1) of E.O. 12866.

FSIS updated the estimated costs for the final rule from those published in the proposed rule from 2021 dollars to 2022 dollars. These changes include: updating the relabeling costs to businesses by updating the 2014 FDA Label Cost Model (FDA Label Cost Model) [35] to 2022 dollars; updating the recordkeeping costs using wage rates for operations managers to 2022 dollars; and updating market testing costs for inflation to 2022 dollars. In response to concerns from commenters on the impact to small businesses, FSIS updated the Regulatory Flexibility Act Assessment with an analysis comparing the final rule's estimated cost for small businesses using U.S.-origin claims to the average revenue for small businesses in the industry. The final rule is expected to result in quantified industry relabeling, recordkeeping, and market testing costs, which combined are estimated to be $3.2 million, annualized at a 7 percent discount rate over 10 years. For comparison, the proposed rule had an estimated cost of $3 million, annualized at a 7 percent discount rate over 10 years.

Need for the Rule

Under current FSIS policy, products with a ''Product of USA'' or similar claim must, at a minimum, have been processed in the United States.[36] For instance, currently, cattle born, raised, slaughtered, and processed in another country may be labeled ''Product of USA'' if the meat was merely further processed in the United States.

This policy may cause false impressions about the origin of FSIS-regulated products in the U.S. marketplace, potentially causing market failures. FSIS has received three petitions from industry associations, each requesting that FSIS address this confusion by revising this policy. The Agency received almost 3,000 public comments in response to these petitions, the majority of which supported altering this policy. FSIS also conducted the RTI survey to gather information on the American consumers' understanding of the meaning of the ''Product of USA'' claim.

In addition, most of the public comments to the proposed rule were in support of the proposed changes.

[33] See FSIS *Directive 7221.1, Rev. 3, Prior Label Approval* (January 18, 2023), available at: *https://www.fsis.usda.gov/policy/fsis-directives/7221.1*.

[34] See FSIS *Uniform Date for Food Labeling Regulations Final Rule* (69 FR 74405, December 14, 2004).

[35] Muth, M., Bradley, S., Brophy, J., Capogrossi, K., Coglaiti, M., & Karns, S. (2015). *2014 FDA labeling cost model.* U.S. Food and Drug Administration.

[36] U.S. Department of Agriculture, Food Safety and Inspection Service. Food Standards and Labeling Policy Book. 2005. *https://www.fsis.usda.gov/guidelines/2005-0003*.

Specifically, over 3,000 consumers, and most domestic producers and organizations, supported the proposed rule, with many citing the need for accurate labeling to ensure that FSIS-regulated products labeled as ''Product of USA'' or ''Made in the USA'' are derived from animals born, raised, slaughtered, and processed in the United States.

Based on the information reviewed by FSIS, the Agency has concluded that the current ''Product of USA'' labeling policy guidance does not reflect consumers' common understanding of what ''Product of USA'' claims mean on FSIS-regulated products. Therefore, the Agency is finalizing regulatory requirements for when the labeling of FSIS-regulated products may bear voluntary claims indicating that the product, or a component of the product's preparation or processing, is of U.S. origin in order to ensure such labels do not mislead or confuse consumers as to the actual origin of FSIS-regulated products.

Baseline for Evaluation of Costs and Benefits

The final rule may require businesses voluntarily using U.S.-origin claims on meat, poultry, and egg product labels to update their labels and conduct increased recordkeeping. FSIS used Label Insight [37] to estimate the number of single and multi-ingredient meat, poultry, and egg product retail labels and the number with an associated U.S.-origin claim.[38]

This analysis identified two types of U.S.-origin claims: (1) Authorized claims, *i.e.,* ''Product of USA'' or ''Made in USA''; and (2) Qualified claims, *e.g.,* ''Raised and Slaughtered in the USA.'' Some of these labels with claims described above are also subject to COOL regulations regarding mandatory labeling depending on the commodity type.[39] To avoid double counting labels, packages with multiple U.S.-origin claims, *e.g.,* ''Product of USA'' on the back display and ''Born and Raised in America'' on the front display, were put into the ''Qualified'' category.

Based on Label Insight data, FSIS identified approximately 98,374 meat, poultry, and egg product retail labels. FSIS then searched the list of 98,374 labels and identified approximately 11,469 with a U.S.-origin type claim, or approximately 12 percent. To account for the possibility of over- or under-estimating the number of relevant labels, this analysis included a lower and upper bound by adjusting the mid-point label estimate minus or plus 10 percent, respectively. As such, FSIS estimates the number of meat, poultry, and egg product retail labels ranges from 88,537 to 108,211 labels and the number of labels with a U.S.-origin claim ranges from 10,322 to 12,616, table 1.[40]

TABLE 1—MEAT, POULTRY AND EGG PRODUCT LABELS [3]

	FSIS labels	U.S.-Origin claims		
		Authorized [1]	Qualified [2]	Total
Low bound	88,537	9,035	1,287	10,322
Mid-point	98,374	10,039	1,430	11,469
Upper bound	108,211	11,043	1,573	12,616

[1] Includes ''Product of USA'' or ''Made in USA.''
[2] Includes detailed U.S.-origin claims, such as ''Born and raised in USA'', and U.S. State and region claims.
[3] The lower and upper bound label estimates are minus or plus 10 percent of the mid-point label estimates.

Expected Costs of the Final Action

The final rule is expected to result in quantified industry relabeling, recordkeeping, and market testing costs, which combined are estimated to cost $3.2 million, annualized at a 7 percent discount rate over 10 years. Details of these cost estimates are provided below.

Relabeling Costs

Under this final rule, FSIS-regulated single ingredient and multi-ingredient products that are not derived from animals born, raised, slaughtered, and processed in the United States will no longer be able to bear the authorized claims of ''Product of USA'' or ''Made in the USA.'' These products will have to be relabeled by either removing the authorized voluntary claim or by using a qualified claim that would describe the production or processing steps that occurred in the United States. For example, a FSIS-regulated product package from an animal not born and raised in the U.S. might replace an authorized claim of ''Product of USA'' with a qualified claim, ''Sliced and packaged in the United States using imported pork.'' Products with a qualified claim might also have to be relabeled to remove or modify the claim, depending on the facts and circumstances of the particular situation.

To estimate the costs associated with relabeling products that will no longer meet the requirements for using their existing labels, this analysis utilized the FDA Label Cost Model [41] and 2022 Label Insight data. The relabeling costs depend on the number of labels required to change, whether the change can be coordinated with a planned label update, and the type of label change (extensive, major, or minor).

As described in the Baseline for Evaluation of Costs and Benefits section, FSIS estimated the number of labels with a U.S.-origin claim. FSIS estimated that a portion of the labels with U.S.-origin claims will modify or remove the claim in response to this final rule as some labels already meet the final and current labeling criteria. However, it is difficult to estimate the number of claims that will change in response to

[37] Label Insight, accessed July 2022. Label Insight is a market research firm that collects data on over 80 percent of food, pet, and personal care products in the U.S. retail market. Data are collected mostly from public web sources and company submissions. See *https://www.labelinsight.com/our-difference/* for more information.

[38] Based on FSIS' labeling expertise, foodservice labels of products sold to hotels, restaurants, and institutions generally do not have a U.S.-origin claim. Therefore, the cost analysis did not include foodservice labels.

[39] *As of 2016, the FSIS-regulated-species and products which are covered commodities under the COOL regulations include muscle cuts of lamb, chicken, and goat; ground lamb, chicken, and goat; and wild and farmed Siluriformes fish.*

[40] To find the meat, poultry, and egg product labels, we first queried the Label Insight data for labels that Label Insight identified as not being in FDA's jurisdiction. We also searched for the terms ''beef'', ''pork,'' and ''chicken'' in the database of labels that Label Insight identified as products under FDA jurisdiction and noted the labels that were in FSIS' jurisdiction. We also examined lamb, mutton, and goat labels but found the number of unique labels were de minimis compared to the number of labels found in the other commodity groups with larger domestic consumption. The label counts include multi- and single ingredient meat, poultry, and egg products.

[41] Muth, M., Bradley, S., Brophy, J., Capogrossi, K., Coglaiti, M., & Karns, S. (2015). *2014 FDA labeling cost model.* U.S. Food and Drug Administration.

the final rule due to data limitations. To account for this uncertainty, FSIS chose a conservative and broad range, with low, mid, and upper bound estimates, to approximate the percentage of product labels that may be relabeled, table 2. The low, mid, and upper bound estimates were calculated by multiplying the low, mid, and upper bound estimated number of labels with a U.S.-origin claim by 25, 50, and 75 percent, respectively.

TABLE 2—NUMBER OF FSIS LABELS THAT WILL BE RELABELED

Estimate	Labels with U.S.-origin claims	Count of labels with changes
Low bound	10,322	2,581
Mid-point	11,469	5,735
Upper bound	12,616	9,462

The number of label changes that can be coordinated with a planned change depends on the compliance time industry has to update labels after the final rule. For the purpose of this analysis, FSIS anticipates the compliance period will be somewhere between 22 and 26 months. Assuming a 24-month compliance period, 100 percent of branded products label updates will be coordinated with a planned label change by that date. However, for private (store brand) labels, only 26 percent will have a coordinated label change, and 74 percent will be uncoordinated.[42] This is because private labels change less frequently than branded labels. This analysis assumed approximately 25 percent of labels are private and 75 percent are branded.[43] Therefore, an estimated 81.5 percent of the labels requiring an update as a result of the rule will have a coordinated change and 18.5 percent will have an uncoordinated change.[44] Based on the FDA Label Cost Model, the label changes that will result from the rule are considered minor. The FDA Label Cost Model defines a minor label change as one where only one color is affected and the label does not need to be redesigned, such as changing an ingredient list or adding a toll-free number.[45]

TABLE 3—TOTAL NUMBER OF FSIS LABELS THAT WILL BE RELABELED AND THE TYPE OF CHANGE

Estimate	Total labels [1]	Private	Branded	Minor coordinated	Minor uncoordinated
Low bound	2,581	645	1,936	2,103	477
Mid-point	5,735	1,434	4,301	4,673	1,061
Upper bound	9,462	2,365	7,097	7,712	1,750

[1] Totals may not sum due to rounding.

The estimates in the FDA Label Cost Model were updated to account for inflation using 2022 producer price indices for the material and consultation costs and 2022 wage rates [46] for the labor hours. The cost estimates in 2022 U.S. dollars are: $874 per label for a minor coordinated change (with a range of $203 [47] to $1,802), and $5,043 per label for a minor uncoordinated change (with a range of $2,222 to $8,968). Combined, the mean estimated relabeling cost is $1.3 million, annualized at a 7 percent discount rate over 10 years, table 4.

TABLE 4—LABELING COSTS WITH A 24-MONTH COMPLIANCE PERIOD IN MILLIONS OF DOLLARS

	Type	Lower	Mean	Upper
Coordinated	Minor	$0.4	$4.1	$13.9
Uncoordinated	Minor	1.1	5.4	15.7
Total Cost.[1]		1.5	9.4	29.6
Annualized Cost (3% DR, 10 Year)		0.2	1.1	3.4
Annualized Cost (7% DR, 10 Year)		0.2	1.3	3.9

[1] Totals may not sum due to rounding.

[42] Muth, M., Bradley, S., Brophy, J., Capogrossi, K., Coglaiti, M., & Karns, S. (2015). *2014 FDA Labeling Cost Model*. U.S. Food and Drug Administration. Table 3–1. Assumed Percentages of Changes to Branded and Private-Label UPCs that Cannot be Coordinated with a Planned Change.

[43] Based on private and branded label estimates for all FSIS labels in the FSIS' Proposed rule, ''Revision of Nutrition Facts Labels for Meat and Poultry Products and Updating Certain Reference Amounts Customarily Consumed'', Published January 19, 2017. *https://www.regulations.gov/document/FSIS-2014-0024-0041*.

[44] For coordinated changes: (75% branded labels × 100% coordinated given 24-month compliance period) + (25% private labels × 26% coordinated given a 24-month compliance period) = 81.5% of FSIS labels can be coordinated with a planned change.

[45] Muth, M., Bradley, S., Brophy, J., Capogrossi, K., Coglaiti, M., & Karns, S. (2015). *2014 FDA Labeling Cost Model*. U.S. Food and Drug Administration. Page 2–9. A major change requires multiple color changes and label redesign, such as adding a facts panel or modifying the front of the package.

[46] Muth, M., Bradley, S., Brophy, J., Capogrossi, K., Coglaiti, M., & Karns, S. (2015). *2014 FDA Labeling Cost Model*. U.S. Food and Drug Administration. Table 4–7. Hourly Wage Rates for Activities Conducted in Changing Product Labels, 2014.

[47] Please note that in comparison to the proposed rule, this number decreased from $205 to $203 because the national wage rate for advertising and promotions managers at the 10th percentile level decreased from $29.45 in 2021 dollars to $29.03 in 2022 dollars. This wage is an input in the FDA Label Cost Model. Estimates obtained from the Bureau of Labor Statistics, May 2022, National Industry-Specific Occupational Employment and Wage Estimates, for advertising and promotions managers (10th percentile)(Occupational Code 11–2011). Advertising and promotion managers (bls.gov)

Recordkeeping Costs

Currently, businesses using labels to designate the U.S.-origin of an FSIS-regulated product, or a component of a product's processing and preparation, must maintain records to support the U.S.-origin claim.[48] Currently, U.S.-origin claims are approved under a generic label approval system. Under the generic approval system, businesses that make products with a U.S.-origin claim are currently estimated to take 15 minutes on average to gather their records, 20 times per year.[49] FSIS estimated that the provisions in this final rule will require businesses to spend an additional 20 minutes (for a combined total of 35 minutes) to gather their records, 20 times per year, per respondent. FSIS acknowledges that it will take substantially more time to document some U.S.-origin claims, such as description of preparation or processing steps, or for U.S.-origin claims on multi-ingredient products. In some cases, establishments can elect to either remove the U.S.-origin claim from the label or make an alternative claim. Due to data limitations, FSIS used brand names associated with a U.S.-origin claim found in Label Insight data to estimate the number of businesses. FSIS estimated that approximately 1,575 brands or businesses have products with U.S.-origin claims and will have additional recordkeeping costs under the final rule. This analysis assumed this recordkeeping will be completed by an operations manager with an hourly estimated cost of $103.24 at the median and a range of wages from ($72.46 to $157.42).[50] As such, the estimated annual cost per business is approximately $688. The estimated annual cost to all 1,575 businesses is approximately $1.1 million, table 5.

TABLE 5—RECORDKEEPING ANNUAL COSTS IN MILLIONS OF DOLLARS

Businesses	Annual number of responses	Minutes per response	Lower	Mid	Upper
1,575	20	20	$0.8	$1.1	$1.7
Annualized Cost (3% DR, 10 Year)		0.8	1.1	1.7	
Annualized Cost (7% DR, 10 Year)		0.8	1.1	1.7	

Market Testing

To assess the marketability of potential label changes, the FDA Label Cost Model includes information on five types of market tests: [51] focus group, discrimination test, central location test, descriptive test, and in-home test. The mean cost for these market tests ranges from $7,788 to $39,497 per formula.[52] The FDA Label Cost Model reports that minor label changes are unlikely to incur any market testing costs.[53] However, some businesses may still want to conduct market testing to assess how consumers will respond to a label change. FSIS estimates that 25 to 75 percent of businesses that have products with U.S.-origin claims will conduct a focus group test on one product formula. FSIS assumed that not every brand will conduct market testing because not every brand will make a change, and such testing is expensive. Additionally, the label changes are expected to be minor, and typically, brands do not conduct market research for minor changes. The estimated cost for a focus group test is $8,035 per formula (with a range of $7,613 to $8,458) in 2022 dollars.[54] Combined, the mean estimated market testing cost is $0.8 million, annualized at a 7 percent discount rate over 10 years, table 6.

TABLE 6—MARKET TESTING COSTS IN MILLIONS OF DOLLARS

	Lower	Mean	Upper
Total Businesses with Market Testing	394	788	1,181
Total Cost [1]	$3.0	$6.3	$10.0
Annualized Cost (3% DR, 10 Year)	0.3	0.7	1.1
Annualized Cost (7% DR, 10 Year)	0.4	0.8	1.3

Cost Summary

Under the provisions in this final rule, industry will likely incur a one-time relabeling cost, market testing cost, and annual recordkeeping costs. Combined and annualized assuming a 7 percent discount rate over 10 years, total industry cost is $3.2 million, table 7.

[48] Businesses with complicated supply lines are not expected to use an authorized claim.

[49] Generic proposed rule: 85 FR 56544, September 14, 2020.

[50] The hourly cost includes a wage rate of $51.62 and a benefits and overhead factor of 2. Estimates obtained from the Bureau of Labor Statistics May 2022, National Industry-Specific Occupational Employment and Wage Estimates, for Management Occupations 50th (25th-75th percentile)(Occupational Code 11–0000), Management Occupations (*bls.gov*)

[51] Mean estimates from the 2014 FDA Label Cost Model were updated to 2022 dollars for inflation. Muth, M., Bradley, S., Brophy, J., Capogrossi, K., Coglaiti, M., & Karns, S. (2015). *2014 FDA Labeling Cost Model*. U.S. Food and Drug Administration. Page 4–43. Table 4–10. Estimated Market Testing Costs in the Labeling Cost Model, 2014 ($/Formula)

[52] Note, a single formula may be represented by more than one UPC because of multiple package sizes or types of packaging. Based Table 4–3 in the FDA Label Cost model, on average, there are approximately 1.17 UPCS per formula for food in NAICS categories 311612, 311615, and 311613.

[53] Muth, M., Bradley, S., Brophy, J., Capogrossi, K., Coglaiti, M., & Karns, S. (2015). *2014 FDA Labeling Cost Model*. U.S. Food and Drug Administration. Page 4–32. For minor labeling changes, ATC [analytical testing costs] and MTC [market testing costs] are likely to be 0.

[54] Muth, M., Bradley, S., Brophy, J., Capogrossi, K., Coglaiti, M., & Karns, S. (2015). *2014 FDA labeling cost model*. U.S. Food and Drug Administration. Page 4–43.

TABLE 7—TOTAL COSTS IN MILLIONS OF DOLLARS

Cost type	Lower	Mean	Upper
Relabeling	$1.5	$9.4	$29.6
Recordkeeping	0.8	1.1	1.7
Market Testing	3.0	6.3	10.0
Annualized Cost (3% DR, 10 Year)	1.3	2.9	6.2
Annualized Cost (7% DR, 10 Year)	1.4	3.2	6.9

Expected Benefit of the Final Rule

The RTI survey results suggest that the current ''Product of USA'' label claim is misleading to a majority of consumers, and consumers believe the ''Product of USA'' claim means the product was made from animals born, raised, and slaughtered, and the meat then processed, in the United States.

From the RTI survey, about 56 percent of survey participants answering the multiple choice question ''To your knowledge, what does the Product of USA label claim on meat products mean?'' thought a ''Product of USA'' claim meant the animal was at least raised and slaughtered and the meat then processed in the United States. Of these participants, 47 percent also believed that the ''Product of USA'' claim indicates that the animal must also be born in the United States, Table 8. Just 16 percent of participants selected the current FSIS policy definition, which only requires that the product be processed in the United States; the animals can be born, raised, and slaughtered in another country. Based on the survey results, the current FSIS ''Product of USA'' labeling guidance does not appear to provide consumers with accurate origin information. These findings suggest that the current ''Product of USA'' label claim is misleading to a majority of consumers. This final rule will adopt a requirement for the ''Product of USA'' claim that will convey more accurate U.S.-origin information and thus reduce consumer confusion in the marketplace.

TABLE 8—PRODUCT OF USA LABEL CLAIM MEANING

Survey Question: To your knowledge, what does the Product of USA label claim on meat products mean?	Percent of responses
(A) Must be made from animals *born, raised,* and *slaughtered* and the meat then *processed* in the USA.	47
(B) Must be made from animals *raised* and *slaughtered* and the meat then *processed* in the USA; the animals can be born in another country	9
(C) Must be made from animals *slaughtered* in the USA; the animals can be born and raised in another country	8
(D) Must be *processed* in the USA; the animals can be born, raised, and slaughtered in another country	16
(E) Not sure/don't know	21

Note: Totals may not sum due to rounding.

The results from the RTI survey also reveal that ''Product of USA'' claims are noticeable and important to consumers. Results from the survey's aided recognition questions show that 70 to 80 percent of eligible consumers correctly recalled seeing the ''Product of USA'' claim. Results from the aided recognition questions also showed that participants correctly recalled the ''Product of USA'' label claim more often than other claims. Results from the survey's unaided recall questions show that about 1 in 3 eligible consumers reported seeing a ''Product of USA'' claim when it was with a U.S. flag icon, while about 1 in 10 eligible consumers reported seeing a ''Product of USA'' claim when it was in plain text included in a list of other claims. These results suggest that consumers frequently notice the ''Product of USA'' label claim. Based on these results, FSIS assumes consumers are interested in ''Product of USA'' claims.

Finally, the RTI study also includes estimates of consumers' MWTP for different U.S.-origin claims using two DCEs. The first DCE asked survey respondents if they were willing to pay more for products with a ''Product of USA'' claim compared to the same product, but with no origin claim. The second DCE asked survey respondents if they were willing to pay different amounts for different definitions on the spectrum of born, raised, slaughtered, and processed in the United States. Each DCE had three product-subgroups: ground beef, NY strip steak, and pork tenderloin. The results from the first DCE show that consumers are willing to pay more for products with a ''Product of USA'' claim, in comparison to similar products without this claim, table 9. Specifically, results comparing products with a ''Product of USA'' claim to ones without such a claim reveal an increase in MWTP per pound of $1.69 for ground beef; $1.71 for pork tenderloin; and $3.21 for NY strip steak, table 9. These results were found to be consistent across income groups.

The results from the second DCE show that in comparison to products that were processed in the United States, consumers have the highest MWTP for products that were born, raised, slaughtered, and processed in the United States, table 9. Specifically, results show a MWTP per pound of $1.15 for ground beef; $1.65 for pork tenderloin; and $3.67 for NY strip steak, for products that were born, raised, slaughtered, and processed in the United States, table 9.

TABLE 9—MWTP FOR PRODUCT OF U.S.-ORIGIN CLAIMS, PER POUND

	Ground beef	Pork tenderloin	NY strip steak
DCE 1 *			
Product of USA	$1.69	$1.71	$3.21
DCE 2 **			
Slaughtered and Processed in the USA	0.30	0.50	1.24
Raised, Slaughtered, and Processed in the USA	0.86	1.24	2.86
Born, Raised, Slaughtered, and Processed in the USA	1.15	1.65	3.67

* Comparing products with a ''Product of USA'' claim versus products without this claim (when no definition was provided).
** Compared to product with a ''Processed in the USA'' claim.

Consumer MWTP estimates, such as those obtained by the RTI survey, rely on stated preferences and may not reflect actual purchasing references in real life situations as the survey respondents do not have their own money on the line. To complement the survey study, FSIS also used a hedonic price model to estimate implicit price premiums of U.S.-origin claims on uniform-weight ground beef products. See Appendix A [55] for the detailed analysis on this hedonic price model. The hedonic price model compared a variable for origin claims linked to the U.S. only and a variable for multi-country origin claims linked to the U.S. plus other countries, to similar products without any U.S.-origin claims [56] on ground beef products. The model found a price premium of 2.5 percent or 10 cents per pound for claims exclusive to U.S. origin. The model found an even higher price premium of 4.2 percent or 16 cents per pound for multi-country origin claims referring to the U.S. and other countries. These implicit price premiums suggest consumers may currently pay more for ground beef products with origin information, including origin claims linked to the U.S. plus other countries, compared to products without any U.S.-origin claims. Based on these results, the estimated price premium for a ground beef product with a U.S.-only origin claim will not decline if the origin claim is modified to include the U.S. and other countries. For context, it should be noted that the estimated price premiums were less than the premiums for other common marketing claims on ground beef products, such as organic, grass-fed, pasture raised, and no antibiotic and no hormone. These marketing claims yielded higher price premiums, ranging from $0.66 to $0.83 per pound, which could suggest that some producers may opt for these types of marketing claims rather than an origin claim. FSIS assumes this relationship holds across other FSIS-regulated product types.

This data from the RTI survey and implicit price premium analysis suggests that consumers have a different understanding of what a ''Product of USA'' claim means when they purchase FSIS-regulated products, compared to the current definition. Consumers expect these labels to convey accurate information about the U.S. origin of the production and preparation of the labeled product based on their understanding of the claim. Without more accurate labeling, consumers may be paying more for products that do not actually conform to their expectations, thus distorting the market.

Benefits Summary

The final ''Product of USA'' regulatory definitions of voluntary U.S.-origin claims align the meaning of those claims with consumers' understandings of the information conveyed by those claims, information that is valued by consumers. The final changes to the ''Product of USA'' voluntary labeling policy are necessary to reduce false or misleading U.S.-origin labeling (See 9 CFR 317.8(a), 381.129(b), and 590.411(f)(1)).[57] This will reduce the market failures associated with incorrect and imperfect information. The final changes will benefit consumers by matching the voluntary authorized ''Product of USA'' and ''Made in the USA'' label claims with the definition that consumers likely expected, *e.g.,* as product being derived from animals born, raised, slaughtered, and processed in the United States.

The benefits for this final rule have not been quantified due to data limitations, and the limitations (some of which are discussed in appendix A) associated with the surveys, LTE experiments, DCEs, and hedonic price modeling. However, the final rule will allow consumers to make informed purchasing decisions, resulting in an increase in consumer benefit and preventing market distortions.

Alternative Regulatory Approaches

We considered the following three alternatives in the analysis for this final rule:

- Alternative 1: Taking no regulatory action by continuing with the existing labeling requirements.
- Alternative 2: The final rule.
- Alternative 3: The final rule, extended compliance period.

TABLE 10—COMPARISON OF THE CONSIDERED ALTERNATIVES

Alternative	Benefits	Cost
1—No Action	No benefit. Misinformation remains	No relabeling costs or increase in recordkeeping costs.

[55] A copy of Appendix A can be found on FSIS' website at: *https://www.fsis.usda.gov/sites/default/files/media_file/documents/Product_of_USA_Appendix.pdf.*

[56] Products without any U.S.-origin claims includes products with no country of origin claim or other country origin claim such as ''Product of Australia.''

[57] FSIS has similar authority under the AMA concerning products receiving voluntary inspection services, as the statute grants the Secretary authority to ''inspect, certify, and identify the class, quality, quantity, and condition of agricultural products when shipped or received in interstate commerce, under such rules and regulations as the Secretary of Agriculture may prescribe, including assessment and collection of such fees as will be reasonable and as nearly as may be to cover the cost of the service rendered, to the end that agricultural products may be marketed to the best advantage, that trading may be facilitated, and that consumers may be able to obtain the quality product which they desire, except that no person shall be required to use the service authorized by this subsection'' (21 U.S.C. 1622(h)(1)).

TABLE 10—COMPARISON OF THE CONSIDERED ALTERNATIVES—Continued

Alternative	Benefits	Cost
2—The Final Rule	More accurate information conveyed more quickly on labels with U.S.-origin claims.	$3.2 million total costs. Relabeling cost $1.3 million. Recordkeeping cost $1.1 million. Market testing cost $0.8 million.
3—Extended Compliance Period.	Reduced benefits because labels with U.S.-origin claims will change at a slower rate and potentially include information that may mislead consumers for an extended period.	$2.6 million total costs. Relabeling cost $0.7 million. Recordkeeping cost $1.1 million. Market testing cost $0.8 million.

Note: Costs are in millions of dollars and annualized at the 7 percent discount rate over 10 years. Numbers may not sum due to rounding.

Alternative 1—Take No Regulatory Action (Baseline)

FSIS considered keeping the current regulations and taking no action. Consumers would be worse off absent the final action. While ''no action'' means the manufacturers currently labeling their products with U.S.-origin claims do not have to relabel or increase recordkeeping activities, and therefore would not incur additional costs, the Agency would fail to address the false impression regarding U.S. origin conveyed by the current ''Product of USA'' labeling requirement. The current claim does not align with consumers' interpretations of what the ''Product of USA'' label claim means.

Therefore, the Agency rejects this alternative.

Alternative 2—The Final Rule

Under this final rule, the authorized claims, ''Product of USA'' and ''Made in the USA'', would only be permitted on the labels of FSIS-regulated products derived from animals born, raised, slaughtered, and processed in the United States. U.S.-origin label claims other than ''Product of USA'' or ''Made in the USA'' would need to include a description of the preparation and processing steps that occurred in the United States upon which the claim is made (as described above). Consumers would benefit from the final changes to the regulations to address the false impression and asymmetric information associated with current U.S.-origin claims.

This is the Agency's preferred alternative.

Alternative 3—The Final Rule, Extended Compliance Period

Alternative 3 would extend the compliance period to 42 months. This alternative reduces both costs and benefits. As shown in Table 11, assuming an extended compliance period of 42-months would provide industry sufficient time to coordinate all required label changes, subsequently reducing annualized relabeling costs by about $0.6 million, as compared to assuming a 24-month compliance period. Recordkeeping and market testing costs would remain the same as alternative 2. The resulting costs would total $2.6 million with relabeling costs of $0.7 million, recordkeeping costs of $1.1 million, and market testing cost of $0.8 million.

However, during this 42-month period, there would be labels with U.S.-origin claims that conform to the current requirements as well as labels that conform to the final new requirements for an extended period. Having U.S.-origin labels that have different, with a mix of old and new, definitions in the marketplace for a prolonged period would increase consumer confusion and market failures.

After the 42-month compliance period, consumers would benefit from the final changes to the regulations to address the false impression and asymmetric information associated with current U.S.-origin claims. Benefits to consumers would be delayed as labels with U.S.-origin claims would change at a slower rate. Therefore, the Agency rejects this alternative.

TABLE 11—TOTAL COSTS 42-MONTH COMPLIANCE

[In millions]

Cost type	Lower	Mean	Upper
Relabeling, One-time	$0.5	$5.0	$17.1
Recordkeeping, Recurring	0.8	1.1	1.7
Market Testing, One-time	3.0	6.3	10.0
Annualized Cost (3% DR, 10 Year)	1.1	2.4	4.7
Annualized Cost (7% DR, 10 Year)	1.2	2.6	5.2

V. Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), this final rule will not have a significant economic impact on a substantial number of small entities in the U.S. Establishments subject to this final rule are classified under the North American Industry Classification System (NAICS) codes 311611-Animal (except Poultry) Slaughter, 311612-Meat Processed from Carcasses, 311615-Poultry Processing, and 311710-Seafood Product Preparation and Packaging.[58] However, not every business under these codes make U.S.-origin claims. To more accurately identify the businesses impacted by this final rule, this analysis used Label Insight Data. Label Insight is a market research firm that collects data on over 80 percent of food, pet, and personal care products in the U.S. retail market. Data are collected mostly from public web sources and company submissions. While Label Insight does not provide information on establishment size or employee counts, FSIS was able to use UPCs and associated brands to estimate the

[58] The Small Business Administration defines a small business in NAICS code 311611- Animal (except Poultry) Slaughter and NAICS code 311612-Meat Processed from Carcasses as having less than 1,000 employees. The NAICS code 311615- Poultry Processing has a small business standard of less than 1,250 employees and NAICS code Seafood Product Preparation and Packaging has a less than 750-employee small business standard.

Small Business Administration (SBA), Table of Small Business Standards, effective March 17, 2023, *https://www.sba.gov/document/support-table-size-standards.*

number of small businesses impacted by the rule. Based on a review of Label Insight data, large brands consistently had over 50 UPCs, while smaller brands consistently had 50 or fewer UPCs. Consequently, FSIS assumed a brand with 50 or fewer UPCs was a small business for the purpose of this analysis.

FSIS estimated that the final rule will impact 1,349 small brands or small businesses. Combined, these 1,349 small businesses have roughly 4,000 labels with U.S.-origin claims. As described above, only a percentage of these labels may need to change as a result of the rule.

FSIS estimated that between 1,000 and 3,000 labels from small business may need changes for the final rule assuming 25, 50, and 75 percent of labels will need to be changed. The average one-time cost estimate for minor label changes is between $874 and $5,043 per label. The expected one-time relabeling cost for 81.5 percent of labels are for minor coordinated changes and are approximately $874 per label. The expected one-time relabeling cost for 18.5 percent of labels are for minor uncoordinated changes, at approximately $5,043 per label.[59]

In addition, businesses will have increased recordkeeping costs. This analysis assumed this recordkeeping will be completed by an operations manager with an estimated hourly cost of $103.24 at the median and a range of wages from $72.46 to $157.427 for 20 minutes, 20 times per year, as described in the Recordkeeping Costs section.[60] [61]

Small businesses may also incur market testing costs. FSIS estimated that 674, with a range between 337 to 1,012, small businesses may conduct market testing, assuming 25, 50, and 75 percent of the 1,349 small businesses conduct market testing. The expected mid-point one-time market testing cost for those small businesses that choose to conduct market testing is $8,035 in 2022 dollars.

The total mid-point cost estimate is $2 million, which is roughly $1,483 per small business ($2 million/1,349 businesses), annualized over 10 years assuming a 7 percent discount rate. Table 12 provides a summary of the estimated total costs to small businesses. FSIS does not have access to proprietary data reflecting the sales volume, including for small businesses voluntarily using U.S.-origin claims, to calculate business profit margins or revenue. However, using data from the U.S. Census Bureau Statistics of U.S. Businesses, FSIS identified small businesses by NAICS codes, which includes the industries affected by the final rule.[62] These small businesses have an average range of revenue of approximately $13 million to $28 million in 2022 dollars based on 2017 receipts adjusted for inflation.[63] The final rule's estimated cost per small business of $1,483 represents 0.005 percent to 0.01 percent of a small business' average revenue.

TABLE 12—TOTAL SMALL BUSINESS COSTS

[In millions of dollars]

Cost type	Lower	Mean	Upper
Relabeling, One-time	$0.6	$3.3	$9.4
Recordkeeping, Recurring	0.7	0.9	1.4
Market Testing, One-time	2.6	5.4	8.6
Annualized Cost (3% DR, 10 Year)	1.1	1.9	3.5
Annualized Cost (7% DR, 10 Year)	1.1	2.0	3.7

VI. Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and recordkeeping requirements included in this final rule have been submitted by the Agency to the Office of Management and Budget (OMB) for approval. FSIS will collect no information associated with this rule until the information collection is approved by OMB.

VII. E-Government Act

FSIS and USDA are committed to achieving the purposes of the E-Government Act (44 U.S.C. 3601, *et seq.*) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizen access to Government information and services, and for other purposes.

VIII. Executive Order 12988, Civil Justice Reform

This final rule has been reviewed under E.O. 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

IX. Executive Order 13175

This rule has been reviewed in accordance with the requirements of E.O. 13175, ''Consultation and Coordination with Indian Tribal Governments.'' E.O. 13175 requires Federal agencies to consult and coordinate with tribes on a government-to-government basis on policies that have tribal implications, including regulations, legislative comments or proposed legislation, and other policy statements or actions that have

[59] Mean estimates from the 2014 FDA Label Cost Model were updated to 2022 dollars for inflation. Muth, M., Bradley, S., Brophy, J., Capogrossi, K., Coglaiti, M., & Karns, S. (2015). *2014 FDA labeling cost model.* U.S. Food and Drug Administration.

[60] The time estimates for recordkeeping per business of 20 minutes, 20 times per year is in addition to the current time estimates for record keeping for U.S.-origin claims, under the generic label approval system. Under the generic label approval system, businesses that make products with a U.S.-origin claim are currently estimated to take 15 minutes on average to gather their records, 20 times per year. Consequently, in total, the estimated time for record keeping for businesses that make products with a U.S.-origin claim would amount to 35 minutes, 20 times per year.

[61] The hourly cost includes a wage rate of $51.62 and a benefits and overhead factor of 2. U.S. Bureau of Labor Statistics (BLS) published May 2022, Occupational Employment and Wage Estimates, 11–0000 Management Occupations, 50th (25th–75th percentile).

[62] Census tabulated data by geography, industry, and enterprise employment or receipts size for most U.S. business establishments by 6-digit NAICS. U.S. Census Bureau, 2017 SUSB Annual Datasets by Establishment Industry, March 2020, *https://www.census.gov/data/datasets/2017/econ/susb/2017-susb.html.*

[63] Estimated small business revenue range based on NAICS codes: 311611-Animal (except Poultry) Slaughter (average revenue of $13 million), 311612-Meat Processed from Carcasses (average revenue of $20 million), 311615—Poultry Processing (average revenue of $28 million), and 311710—Seafood Product Preparation and Packaging (average revenue of $22 million). U.S. Census Bureau, 2017 SUSB Annual Datasets by Establishment Industry, March 2020, *https://www.census.gov/data/datasets/2017/econ/susb/2017-susb.html.* Updated for inflation using BLS Consumer Price Index (CPI), All items in U.S. city average, all urban consumers, not seasonally adjusted (CUUR0000SA0 Not Seasonally Adjusted).

substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

FSIS has assessed the impact of this rule on Indian tribes and determined that this rule does not, to our knowledge, have tribal implications that require tribal consultation under E.O. 13175. If a tribe requests consultation, FSIS will work with the Office of Tribal Relations to ensure meaningful consultation is provided where changes, additions, and modifications identified herein are not expressly mandated by Congress.

X. USDA Non-Discrimination Statement

In accordance with Federal civil rights law and USDA civil rights regulations and policies, USDA, its Mission Areas, agencies, staff offices, employees, and institutions participating in or administering USDA programs are prohibited from discriminating based on race, color, national origin, religion, sex, gender identity (including gender expression), sexual orientation, disability, age, marital status, family/parental status, income derived from a public assistance program, political beliefs, or reprisal or retaliation for prior civil rights activity, in any program or activity conducted or funded by USDA (not all bases apply to all programs). Remedies and complaint filing deadlines vary by program or incident.

Program information may be made available in languages other than English. Persons with disabilities who require alternative means of communication to obtain program information (*e.g.,* Braille, large print, audiotape, American Sign Language) should contact the responsible Mission Area, agency, or staff office; the USDA TARGET Center at (202) 720–2600 (voice and TTY); or the Federal Relay Service at (800) 877–8339.

To file a program discrimination complaint, a complainant should complete a Form, AD–3027, *USDA Program Discrimination Complaint Form,* which can be obtained online at *https://www.usda.gov/forms/electronic-forms,* from any USDA office, by calling (866) 632–9992, or by writing a letter addressed to USDA. The letter must contain the complainant's name, address, telephone number, and a written description of the alleged discriminatory action in sufficient detail to inform the Assistant Secretary for Civil Rights about the nature and date of an alleged civil rights violation. The completed AD–3027 form or letter must be submitted to USDA by: (1) Mail: U.S. Department of Agriculture, Office of the Assistant Secretary for Civil Rights, 1400 Independence Avenue SW, Washington, DC 20250–9410; or (2) Fax: (833) 256–1665 or (202) 690–7442; or (3) Email: *program.intake@usda.gov.*

USDA is an equal opportunity provider, employer, and lender.

XI. Environmental Impact

Each USDA agency is required to comply with 7 CFR part 1b of the Departmental regulations, which supplements the National Environmental Policy Act regulations published by the Council on Environmental Quality. Under these regulations, actions of certain USDA agencies and agency units are categorically excluded from the preparation of an Environmental Assessment (EA) or an Environmental Impact Statement (EIS) unless the agency head determines that an action may have a significant environmental effect (7 CFR 1b.4 (b)). FSIS is among the agencies categorically excluded from the preparation of an EA or EIS (7 CFR 1b.4 (b)(6)).

FSIS has determined that this final rule, which will establish voluntary labeling requirements for FSIS-regulated products with ''Product of USA,'' ''Made in the USA,'' and similar claims, will not create any extraordinary circumstances that would result in this normally excluded action having a significant individual or cumulative effect on the human environment. Therefore, this action is appropriately subject to the categorical exclusion from the preparation of an environmental assessment or environmental impact statement provided under 7 CFR 1b.4(6) of the U.S. Department of Agriculture regulations.

XII. Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication on-line through the FSIS web page located at: *https://www.fsis.usda.gov/federal-register.*

FSIS will also announce and provide a link through the FSIS *Constituent Update,* which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an email subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: *https://www.fsis.usda.gov/subscribe.* Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves and have the option to password protect their accounts.

List of Subjects

9 CFR Part 317

Food labeling, Food packaging, Meat inspection, Nutrition, Reporting and recordkeeping requirements.

9 CFR Part 381

Poultry inspection, Poultry and poultry products, Reporting and recordkeeping requirements.

9 CFR Part 412

Food labeling, Food packaging, Meat and meat products, Meat inspection, Poultry and poultry products, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, FSIS is amending 9 CFR chapter III as follows:

PART 317—LABELING, MARKING DEVICES, AND CONTAINERS

■ 1. The authority citation for part 317 continues to read as follows:

Authority: 21 U.S.C. 601–695; 7 CFR 2.18, 2.53.

■ 2. Amend § 317.8 by revising paragraph (b)(1) to read as follows:

§ 317.8 False or misleading labeling or practices generally; specific prohibitions and requirements for labels and containers.

* * * * *

(b) * * *

(1) Establishments may only use statements, words, pictures, designs, or devices on the label having geographical significance with reference to a locality other than where the animal from which the product was derived was born, raised, slaughtered, and processed if the statements, words, pictures, designs, or devices are qualified by the word ''style,'' ''type,'' or ''brand,'' as the case may be, in the same size and style of lettering as in the geographical statement, word, picture, design, or device, and accompanied with a prominent qualifying statement identifying the country, State, Territory, or locality, using terms appropriate to effect the qualification. When the word ''style'' or ''type'' is used, there must be a recognized style or type of product

identified with and peculiar to the area represented by the geographical statement, word, picture, design, or device and the product must possess the characteristics of such style or type, and the word ''brand'' shall not be used in such a way as to be false or misleading: Provided, That a geographical statement, word, picture, design, or device which has come into general usage as a trade name and which has been approved by the Administrator as being a generic statement, word, picture, design, or device may be used without the qualifications provided for in this paragraph. The terms ''frankfurter,'' ''vienna,'' ''bologna,'' ''lebanon bologna,'' ''braunschweiger,'' ''thuringer,'' ''genoa,'' ''leona,'' ''berliner,'' ''holstein,'' ''goteborg,'' ''milan,'' ''polish,'' ''italian,'' and their modifications, as applied to sausages, the terms ''brunswick'' and ''irish'' as applied to stews and the term ''boston'' as applied to pork shoulder butts need not be accompanied with the word ''style,'' ''type,'' or ''brand,'' or a statement identifying the locality in which the product is prepared.

* * * * *

PART 381—POULTRY PRODUCTS INSPECTION REGULATIONS

■ 3. The authority citation for part 381 continues to read as follows:

Authority: 7 U.S.C. 1633, 1901–1906; 21 U.S.C. 451–472; 7 CFR 2.7, 2.18, 2.53.

■ 4. Amend § 381.129 by revising paragraph (b)(2) to read as follows:

§ 381.129 False or misleading labeling or containers.

* * * * *

(b) * * *

(2) Statements, words, pictures, designs, or devices having geographical significance with reference to a particular locality must be made in accordance with § 317.8(b)(1) of this chapter.

* * * * *

PART 412—LABEL APPROVAL

■ 5. The authority citation for part 412 continues to read as follows:

Authority: 21 U.S.C. 451–470, 601–695; 7 CFR 2.18, 2.53.

■ 6. Section 412.3 is added to read as follows:

§ 412.3 Approval of U.S.-origin generic label claims.

(a) The claims ''Product of USA'' and ''Made in the USA'' may be used under generic approval on labels to designate single ingredient products derived from animals born, raised, slaughtered, and processed in the United States.

(b)(1) The claims ''Product of USA'' and ''Made in the USA'' may be used under generic approval on labels to designate multi-ingredient products if:

(i) All ingredients that are produced under FSIS mandatory inspection or voluntary inspection services in the product are derived from animals born, raised, slaughtered, and processed in the United States;

(ii) All other ingredients in the product are of domestic origin; and

(iii) The preparation and processing steps for the multi-ingredient product have occurred in the United States.

(2) For purposes of this paragraph (b), spices and flavorings need not be of domestic origin for claim use, but all other ingredients of the product must be of domestic origin.

(c) Claims other than ''Product of USA'' and ''Made in the USA'' may be used under generic approval on labels to designate the U.S.-origin component of single ingredient and multi-ingredient products' preparation and processing only if the claim includes a description of the preparation and processing steps that occurred in the United States upon which the claim is being made. Such labels must be truthful and not misleading.

(d) Claims may be used under generic approval on labels to designate the U.S. State, Territory, or locality-origin of single ingredient and multi-ingredient products or components of a product's preparation and processing, only if the claim meets the requirements for use of U.S.-origin claims under paragraphs (a) through (c) of this section with regards to the U.S. State, territory, or locality origin.

(e) Display of the U.S. flag, or a U.S. State or territory flag, may be used under generic approval on labels 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, only if the display of the flag meets the requirements for use of U.S.-origin claims under paragraphs (a) through (d) of this section. 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 paragraph (c) or (d) of this section, 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 or territory, upon which the claim is being made.

(f) In addition to the requirements in § 412.2, official establishments using and facilities choosing to use labels that bear the claims ''Product of USA'' or ''Made in the USA'' to designate products of U.S. origin must maintain records to support the U.S.-origin claim. Examples of the types of documentation that may be maintained to support the U.S.-origin claims ''Product of USA'' or ''Made in the USA'' include:

(1) A written description of the controls used in the birthing, raising, slaughter, and processing of the source animals and eggs, and for multi-ingredient products the preparation and processing of all additional ingredients other than spices and flavorings, to ensure that each step complies with paragraphs (a) and (b) of this section.

(2) 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 eggs, all additional ingredients other than spices and flavorings, and resulting products that comply with paragraphs (a) and (b) of this section.

(3) A signed and dated document describing how the product is prepared and processed to support that the claim is not false or misleading.

(g) In addition to the requirements in § 412.2, official establishments using and facilities choosing to use a U.S.-origin label claim other than ''Product of USA'' or ''Made in the USA'' to designate the U.S.-origin preparation and processing steps of a product must maintain records to support the qualified U.S.-origin claim. Examples of the types of documentation that may be maintained to support the qualified U.S.-origin claim include:

(1) A written description of the controls used in each applicable preparation and processing step of source animals and eggs, all additional ingredients other than spices and flavorings, and resulting products to demonstrate that the qualified U.S.-origin claim complies with paragraph (c) or (d) of this section. The described controls may include those used to trace and, as necessary, segregate, during each applicable step, source animals and eggs, all additional ingredients other than spices and flavorings, and resulting products that comply with the U.S.-origin claim from those that do not comply.

(2) A signed and dated document describing how the qualified U.S.-origin claim regarding the preparation and processing steps is not false or misleading.

Done in Washington, DC.

Theresa Nintemann,

Deputy Administrator.

[FR Doc. 2024–05479 Filed 3–15–24; 8:45 am]

BILLING CODE 3410–DM–P