Proposed Rules

Federal Register
Vol. 88, No. 48
Monday, March 13, 2023

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 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: Proposed rule.

SUMMARY: FSIS is proposing to amend its 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 United States origin. The Agency is taking this action to resolve consumer confusion surrounding current voluntary label claims related to the origin of FSIS-regulated products in the U.S. marketplace. Under this proposal, establishments would not need to include these claims on the label, but if they chose to include them, they would need to meet the requirements in this rule.

DATES: Comments must be received on or before May 12, 2023.

ADDRESSES: FSIS invites interested persons to submit comments on this proposed rule. 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.
- *Hand- or Courier-Delivered Submittals:* Deliver to 1400 Independence Avenue SW, Jamie L. Whitten Building, Room 350–E, 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) 937–4272 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, Food Safety and Inspection Service, U.S. Department of Agriculture; Telephone: (202) 937–4272.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Executive Summary
II. Background
  A. Statutory and Regulatory Requirements for the Labeling of FSIS-Regulated Products
  B. Current FSIS Policy on ''Product of USA'' and Similar Label Claims
  C. Petitions for Rulemaking
  D. Consumer Survey
III. Proposed Rule
IV. Executive Orders 12866 and 13563
  A. Economic Impact Analysis
  B. Regulatory Flexibility Act Assessment
V. Paperwork Reduction Act
VI. E-Government Act
VII. Executive Order 12988, Civil Justice Reform
VIII. Executive Order 13175
IX. USDA Non-Discrimination Statement
X. Environmental Impact
XI. Additional Public Notification
XII. Proposed Rule Text

I. Executive Summary

To prevent the introduction of adulterated or misbranded products into commerce, FSIS implements a prior approval program for labels intended to be used on FSIS-regulated products (9 CFR part 412). Without approved labels, these products may not be sold, offered for sale, or otherwise distributed in commerce.

Certain categories of labels must be submitted to FSIS for review and approval before use on products in commerce. However, FSIS considers certain labels that comply with the Agency's labeling rules to be ''generically'' approved (9 CFR 412.2). Such labels are not submitted to FSIS, because they are deemed approved if they bear all applicable mandatory labeling features and are not false or misleading, and may be applied to product in commerce, provided that supporting documentation for any information on the label is part of the labeling record. One category of labels currently eligible for generic approval is labels bearing U.S.-origin claims, like ''Product of USA.''

FSIS recently 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. FSIS started this review after receiving several petitions stating that the voluntary label claim ''Product of USA'' is confusing to consumers. By law, no product may bear any false or misleading label, such as labeling which conveys any false impression or gives any false indication of origin. FSIS' review of the policy included a consumer survey on ''Product of USA'' labeling on beef and pork products. Based on the consumer survey results, reviews of consumer research, and comments received on the petitions, FSIS is proposing to amend its regulations to define the conditions under which voluntary claims may be used on the labels of meat, poultry, and egg products, as well as voluntarily-inspected products, to indicate that the products are of U.S. origin.

Under this proposed rule, two specific voluntary U.S.-origin label claims, ''Product of USA'' and ''Made in the USA'' (the ''authorized claims''), would be generically approved for use on single ingredient, FSIS-regulated products derived from animals born, raised, slaughtered, and processed in the United States. The two voluntary authorized label claims ''Product of USA'' and ''Made in the USA'' would also be generically approved for use on multi-ingredient FSIS-regulated products if: (1) All FSIS-regulated components of the product are derived from animals born, raised, slaughtered, and processed in the United States; and (2) All additional ingredients, other than spices and flavorings, are of domestic

origin (*i.e.,* all preparation and processing steps of the ingredients are completed in the United States).

This proposed rule would also allow for U.S.-origin label claims other than the two authorized claims ''Product of USA'' and ''Made in the USA.'' All U.S.-origin label claims that are not authorized claims are known as ''qualified claims.'' These qualified claims would need to include a description on the package of all preparation and processing steps (including slaughter) that occurred in the United States upon which the claim is made.[1] These would need to be positioned near the qualified claim and explain how the product compares to the regulatory criteria for use of the two authorized claims ''Product of USA'' and ''Made in the USA.'' For example, ''Sliced and packaged in the United States using imported pork'' could be a qualified claim. As with the two authorized claims ''Product of USA'' and ''Made in the USA,'' all qualified claims that meet the proposed regulatory requirements would be eligible for generic approval. The proposed rule would apply to domestic products.[2] For product exported from the United States, FSIS would continue to verify that labeling requirements for the applicable country are met, as shown in the FSIS Export Library.[3]

Establishments producing products covered by USDA's Agricultural Marketing Service's (AMS) Country of Origin (COOL) mandatory labeling regulations (see 7 CFR parts 60 and 65) would still need to comply with COOL requirements (see 9 CFR 317.8(b)(40)). AMS' COOL requires retailers, such as full-line grocery stores, supermarkets and club warehouse stores, to notify their customers with information regarding the source of certain foods.[4] Should this rule become final, any FSIS-regulated product that is also a commodity subject to COOL requirements must continue to comply with those requirements.

Section IV below contains an analysis of the proposed rule's expected costs and benefits, an explanation of the assumptions, alternative scenarios, and the expected impact on small businesses. The requirements in this proposed rule, if finalized, are estimated to result in a one-time relabeling cost for industry, annual recordkeeping costs, and one-time market testing costs. Combined and annualized assuming a 7-percent discount rate over 10 years, the total estimated industry cost would be $3 million. The proposed 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 proposed changes to the ''Product of USA'' voluntary labeling policy are intended to prevent false or misleading U.S.-origin labeling (see 9 CFR 317.8(a), 381.129(b), 590.411(f)(1)).[5] This would reduce the market failures associated with incorrect and asymmetric information. The proposed changes would benefit consumers by matching the voluntary authorized ''Product of USA'' and ''Made in the USA'' label claims with the definition that consumers likely expected (*i.e.,* product derived from animals born, raised, slaughtered, and processed in the United States). If finalized, the proposed changes would allow consumers to make informed purchasing decisions, resulting in an increase in consumer benefits and preventing market failures as shoppers will be better able to choose products according to their preferences.

II. 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. 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). The requirements proposed under this rule for the two voluntary authorized claims ''Product of USA'' and ''Made in the USA'' and voluntary qualified U.S.-origin claims would apply to all products subject to FSIS' mandatory inspection or that are inspected under the voluntary inspection services provided by FSIS.[6] Establishments would not need to include these claims on the label, but if they chose to include them, they would need to meet the requirements in this proposed rule.

Under the mandates of 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

[1] In this proposed rule, the Agency is using both terms ''preparation'' and ''processing'' for clarity and completeness. The term ''prepared'' is defined in the meat regulations as ''slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed'' (See 9 CFR 301.2). The term ''process'' is defined in the poultry regulations as ''a means to conduct any operation or combination of operations, whereby poultry is slaughtered, eviscerated, canned, salted, stuffed, rendered, boned, cut up, or otherwise manufactured or processed'' (See 9 CFR 381.1). The term ''processing'' is defined in the egg products regulations as ''manufacturing of egg products, including breaking eggs or filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing or drying, or packaging or repackaging egg products at official plants''(See 9 CFR 590.5).

[2] As discussed below, 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 would be subject to the proposed regulatory requirements.

[3] All federally inspected and passed products are eligible to receive export certification by FSIS if all FSIS and foreign country requirements listed in the FSIS Export Library have been met. Certain deviations from domestic product requirements or label policies are allowed, in accordance with 9 CFR 312.8, 322.1 through 322.5, 350.3(b), 362.2(b), 381.104 through 381.111, and 590.402.

[4] The FSIS-regulated products that are also COOL covered commodities are ground and muscle cuts of lamb, chicken and goat (7 CFR 65.135) and Siluriformes fish (7 CFR 60.106). COOL covered commodities meeting the regulatory definition of ''processed food item(s)'' are exempted from mandatory country of origin labeling (7 CFR 60.119 and 7 CFR 65.220).

[5] 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'' (7 U.S.C. 1622(h)(1)).

[6] 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).

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)).[7]

As discussed below, and as explained in the FSIS Food Standards and Labeling Policy Book (''Food Standards and Labeling Policy Book''),[8] FSIS-regulated products that are derived from animals that may have been born, raised, and slaughtered in another country but are minimally processed in the United States may currently be labeled as ''Product of USA.'' The United States imports live animals, carcasses, and other products that are incorporated into U.S. preparation and marketing of meat products.

However, this policy may be causing false impressions about the origin of FSIS-regulated products in the U.S. marketplace. In July 2021, Secretary Vilsack announced that USDA would comprehensively review the current ''Product of USA'' labeling policy for products that FSIS regulates.[9] The review was intended to help the Agency determine what the ''Product of USA'' label means to consumers. To make sure that customers had access to accurate and clear labels, Executive Order 14036, *Promoting Competition in the American Economy* (86 FR 36987, July, 14, 2021) called for a rulemaking on voluntary ''Product of USA'' labeling for meat products.

[7] 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'' (7 U.S.C. 1622(h)(1)).

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

[9] USDA Release No. 0151.21, ''USDA Announces Efforts to Promote Transparency in Product of the USA Labeling,'' available at: *https://www.usda.gov/media/press-releases/2021/07/01/usda-announces-efforts-promote-transparency-product-usa-labeling*.

In his announcement, Secretary Vilsack cited the U.S. Federal Trade Commission (FTC) final rule, thereafter published on July 14, 2021, related to ''Made in USA'' and other unqualified U.S.-origin claims on products sold in the United States (86 FR 37022). 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.

A. Statutory and Regulatory Requirements for the Labeling of FSIS-Regulated Products

Labeling of Products Generally

As discussed above, under certain circumstances, FSIS regulations allow product labels that bear all required labeling features and comply with the Agency's labeling regulations to be ''generically approved'' (9 CFR 412.2(a)(1)). Labels that are generically approved may be used in commerce without prior submission to the Agency for approval. FSIS inspection program personnel (IPP) perform inspection tasks at establishments to verify that generically approved labels comply with labeling requirements.[10] Official establishments, therefore, do not need to submit generically approved labels to FSIS for evaluation. Current FSIS regulations allow all geographic and country of origin claims on labels of FSIS-regulated products, including ''Product of USA'' and similar U.S.-origin claims (9 CFR 412.2(b)), to be generically approved.

Labeling of Imported Products

FSIS' regulations require that the immediate container of imported meat, poultry, and eggs products to bear the name of the country of origin, preceded by the words ''Product of'' (9 CFR 327.14, 381.205, 590.950). If such imported products are intended to be sold at retail, the original packaging with the ''product of country'' labeling must remain with the product. However, if these products are repackaged or otherwise reprocessed in a federally inspected facility, they are currently deemed and treated as domestic product for both mandatory and voluntary labeling purposes.[11] Therefore, because such products are treated as domestic products for labeling purposes, under current FSIS labeling policy for U.S.-origin claims, they no longer are required to meet FSIS' mandatory origin labeling requirements for imported products (see Food Standards and Labeling Policy Book).

[10] For example, under FSIS Directive 7221.1, Rev. 3 (January 31, 2023), IPP are directed to routinely include generic labels as part of the general labeling inspection tasks. These tasks, which include factual statement verification, take place approximately five to six times monthly in each inspected establishment or facility.

[11] In a 1989 final rule clarifying these provisions, FSIS stated that ''[o]nce product offered for entry has been reinspected by FSIS inspectors and the official mark of inspection has been applied, FSIS considers that such product has been 'entered' into the United State and, therefore, is the regulatory equivalent of domestic product.'' (54 FR 41045, October 5, 1989).

B. Current FSIS Policy on ''Product of USA'' and Similar Label Claims

The Food Standards and Labeling Policy Book provides guidance addressed to how manufacturers may prepare meat and poultry product labels that are truthful and not misleading. The Food Standards and Labeling Policy Book guidance for labeling products with ''Product of USA'' or similar claims currently states that labeling of a meat or poultry product may bear the phrase under one of two conditions, (1) if the country to which the product is exported requires this phrase, and the product is processed in the United States, or (2) the product is processed in the United States.[12] This U.S.-origin labeling guidance applies to ''Product of USA'' claims made with respect to multi-ingredient FSIS-regulated products, as well as single ingredient FSIS-regulated products. Thus, currently, a product may bear the ''Product of USA'' claim if the product is processed in the United States, or if the country to which the product is exported requires it and the product is processed in the United States.

In May 2003, a revision to the Food Standards and Labeling Policy Book cancelled an April 1985 FSIS policy memorandum that advised that a label of a FSIS product could include the ''Product of USA'' claim if it could be demonstrated that all ingredients having a bearing on consumer preference, such as meat, vegetables, fruits, and dairy products, were of domestic origin.

C. Petitions for Rulemaking

USDA has received three petitions from industry associations regarding the origin of meat products bearing the ''Product of USA'' label claim, each requesting that FSIS formally revise its Food Standards and Labeling Policy Book guidance for such claims.

Organization for Competitive Markets (OCM) and the American Grassfed Association (AGA) Petition

In June 2018, FSIS received a petition, submitted on behalf of OCM and AGA, requesting that FSIS amend the Food

[12] The FSIS poultry regulations at 9 CFR 381.1 define ''process'' as ''a means to conduct any operation or combination of operations, whereby poultry is slaughtered, eviscerated, canned, salted, stuffed, rendered, boned, cut up, or otherwise manufactured or processed.'' The FSIS meat regulations at 9 CFR 301.2 include ''processed'' in the definition of ''prepared'' (*i.e.,* ''slaughtered, canned, salted, rendered, boned, cut up, or otherwise manufactured or processed.'') The FSIS egg products regulations at 9 CFR 590.5 define ''processing'' as the means of ''manufacturing of egg products, including breaking eggs or filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing or drying, or packaging or repackaging egg products at official plants.''

Standards and Labeling Policy Book 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.[13] The petition asserted that the Agency's current policy has resulted in labeling that is misleading to consumers because it allows imported meat that is reprocessed in the United States to be labeled as ''Product of USA.'' The petition further asserted that when imported meat products that have been further processed in an official U.S. establishment are labeled as ''Product of USA,'' consumers that prefer domestic meat cannot make an informed choice because the labeling disguises the true origin of the product. Finally, the petition asserted that the current policy also caused financial harm to U.S. family farmers and independent ranchers by giving an unfair market advantage to companies that further process imported meat.

FSIS received 2,593 public comments on the OCM/AGA petition.[14] A majority of the comments expressed support for the petition, stating that the use of ''Product of USA'' labeling should be limited to products from livestock that were born, raised, and slaughtered in the United States. Most were comments submitted by individual consumers, farmers, and ranchers, as well as trade associations representing these groups, labor unions, and animal welfare advocacy organizations. Several comments stated that the term ''Product of USA'' implies that the product was derived from livestock that were born, raised, and slaughtered in the United States and, therefore, is misleading when applied to imported products that have been further processed in an official U.S. establishment. Many of the comments stated that the current policy gives certain companies that import foreign grass-fed beef an unfair economic advantage.

Comments from other cattle producer trade associations, meat processor trade associations, Canadian and Mexican livestock producer trade associations, and the Canadian and Mexican governments did not support the petition. These comments stated that FSIS' ''Product of USA'' labeling policy has never been limited to livestock born, raised, and slaughtered in the United States. Comments from the Canadian and Mexican governments noted that the Canadian and U.S. livestock industries, and the Mexican and U.S. cattle industries, are highly integrated, and that both Canada and Mexico export a significant number of live cattle into the United States each year for feeding, slaughter, and processing. The comments expressed concerns about changes in labeling that could potentially disrupt these integrated livestock supply chains. No other foreign entities submitted comments.

On March 26, 2020, FSIS responded to the OCM/AGA petition, stating that the Agency had decided to initiate rulemaking to define the conditions under which the labeling of meat products would be permitted to bear voluntary claims that indicate that the product is of U.S. origin, such as ''Product of USA'' or ''Made in the USA.'' [15] FSIS stated that, after considering the petition and the public comments received on the petition, the Agency concluded that its current labeling policy, which permits meat and poultry products that were derived from animals that may have been born, raised, and slaughtered in another country but processed in the United States to be labeled as ''Product of USA,'' may be causing confusion in the marketplace, particularly with respect to certain imported meat products, and that the Agency intended to propose that such labeling be limited to meat products derived from livestock that were slaughtered and processed in the United States.

United States Cattlemen's Association (USCA) Petition

In October 2019, USCA submitted a petition requesting that FSIS amend the Food Standards and Labeling Policy Book to provide that any beef product voluntarily-labeled as ''Made in the USA,'' ''Product of the USA,'' ''USA Beef'' or in any other manner that suggests that the origin is the United States, be derived from cattle that have been born, raised, and slaughtered in the United States.[16] As with the OCM/AGA petition, the USCA petition asserted that FSIS' current policy is misleading because it allows imported meat products processed in the United States to be labeled as ''Product of USA.'' The petition further asserted that consumers expect beef products labeled as ''Product of USA'' to be from cattle that were born, raised, and slaughtered in the United States. Finally, the petition referenced several studies that, according to the petition, demonstrated that U.S. consumers are interested in knowing the country of origin of beef products and are willing to pay a premium for meat from animals born, raised, and slaughtered in the United States.

FSIS received 111 public comments on the USCA petition.[17] A majority of the comments expressed support for the petition, stating that the use of ''Product of USA'' labeling should be limited to products from livestock that were born, raised, and slaughtered in the United States. Most were comments submitted by individual consumers, farmers, and ranchers, as well as trade associations representing these groups. Several comments stated that the term ''Product of USA'' implies that the product was derived from livestock that were born, raised, and slaughtered in the United States and, therefore, is misleading when applied to imported products that have been further processed in the United States. Comments from some cattle producer trade associations, meat processor trade associations, Canadian and Mexican livestock producer trade associations, and the Canadian and Mexican governments did not support the petition. Similar to the comments on the OCM/AGA petition, these comments stated that FSIS' ''Product of USA'' labeling policy has never been limited to livestock born, raised, and slaughtered in the United States. Comments from the Canadian and Mexican governments noted again that the Canadian and U.S. livestock industries, and the Mexican and U.S. cattle industries, are highly integrated, and that both Canada and Mexico export a significant number of live cattle into the United States each year for feeding, slaughter, and processing. The comments expressed concerns about measures that could potentially disrupt these integrated livestock supply chains. No other foreign entities submitted comments.

As with FSIS' response to the OCM/ACA petition, on March 26, 2020, FSIS responded to the USCA petition to state that the Agency had decided to initiate rulemaking to define the conditions under which the labeling of meat products would be permitted to bear

[13] FSIS Petition 18–05, Petition for Change to the FSIS Standards and Labeling Policy Book on ''Product of U.S.A.'' (June 12, 2018), available at: *https://www.fsis.usda.gov/federal-register/petitions/petition-change-fsis-standards-and-labeling-policy-book-product-usa.*

[14] Comments submitted on Petition 18–05 available at: *https://www.regulations.gov/document/FSIS-2018-0024-0001/comment.*

[15] Response to Petition 18–05 available at: *https://www.fsis.usda.gov/sites/default/files/media_file/2020-07/18-05-fsis-final-response-032620.pdf.*

[16] FSIS Petition 19–05, Petition for the Imposition of Beef Labeling Requirements to Address ''Made in USA'' Claims (October 23, 2019), available at: *https://www.fsis.usda.gov/federal-register/petitions/petition-imposition-beef-labeling-requirements-address-made-usa-claims.*

[17] Comments submitted on Petition 19–05 available at: *https://www.regulations.gov/document/FSIS-2019-0024-0001/comment.*

voluntary claims that indicate that the product is of U.S. origin, such as ''Product of USA'' or ''Made in the USA.'' [18] Also, similar to the response to the OCM/ACA petition, FSIS stated the Agency's conclusion that its current labeling policy may be causing confusion in the marketplace, particularly with respect to certain imported meat products, and that the Agency intended to propose that such labeling be limited to meat products derived from livestock that were slaughtered and processed in the United States.

National Cattlemen's Beef Association (NCBA) Petition

After FSIS considered and responded to the OCM/AGA and USCA petitions in March 2020, NCBA submitted a petition in June 2021 requesting that FSIS initiate rulemaking to amend the Agency's labeling regulations to eliminate the broadly applicable ''Product of USA'' label claim but to allow for other label claims.[19] Specifically, the petition requested that FSIS initiate rulemaking to amend its regulations to state that single ingredient beef products or ground beef may be labeled as ''Processed in the USA,'' provided that the label displays all mandatory features and is not otherwise false or misleading. Further, the petition requested that FSIS amend its regulations to state that other claims relating to U.S. origin, production, or processing of meat products are not eligible for generic approval. Similar to the AGA/OCM and USCA petitions, the NCBA petition generally asserted that the Agency's current policy on U.S.-origin labeling furthers consumer confusion as to whether products with U.S.-origin label claims are derived from animals born, raised, and slaughtered in the United States.

FSIS received 261 public comments on the NCBA petition.[20] Most comments did not support the petition, stating that replacing the current ''Product of USA'' labeling policy with a ''Processed in the USA'' label would not resolve the issue of consumer confusion about the origin of beef products. Many comments instead suggested that changing the definition of ''Product of USA'' to require that the beef product be derived from cattle born, raised, and slaughtered in the United States would better resolve consumer confusion. Other comments supported adding a specific ''born in the United States'' requirement to the Agency's current ''Product of USA'' labeling requirements for beef products. These comments were mostly submitted by individual consumers, ranchers, and those in communities supported by the cattle industry. Comments expressed concern about consumer choice and some stated an interest in supporting American cattle ranchers. Other comments submitted by trade associations and advocacy groups related to the cattle industry stated that a change to the definition of ''Product of USA'' would better address the issues raised in the petition. Additionally, the Canadian and Mexican governments each provided public comments that did not support the petition and focused on maintaining integrated livestock supply chains between the United States and their respective cattle markets. Each government specifically noted their interest in cooperation with any change to U.S. labeling practices as to avoid disruptions in the supply chain. No other foreign entities submitted comments.

The publication of this proposed rule serves as the Agency's response to the issues raised by all three related petitions.

D. Consumer Survey

To gather additional information as part of FSIS' comprehensive review of the current voluntary ''Product of USA'' label claim, on February 1, 2022, FSIS requested approval for a new information collection to conduct a consumer web-based survey on ''Product of USA'' labeling on beef and pork products (87 FR 5455). On June 13, 2022, the U.S. Office of Management and Budget (OMB) approved the survey, and on August 14, 2022, RTI International completed administration of the survey (''RTI survey''). The final report [21] 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.*

The target population for the survey was the U.S. general population of adults (18 years or older) who speak English or Spanish, were primarily responsible for the grocery shopping in their household, and had purchased beef or pork in the last six months. The survey was administered over the web,[22] using a probability-based panel designed to be representative of the U.S. adult population and whose panel members were recruited using address-based sampling and weighting procedures to provide nationally representative estimates. The use of web-based data collection expedited the timeliness of data collection and allowed the study to reach a more diverse study population. Approximately 4,842 individuals took the survey, including 311 who completed the survey in the Spanish language.

The study used beef and pork products. In addition, the study considered high-cost beef products (*i.e.,* steak) and lower-cost beef products (*i.e.,* ground beef) to capture any potential differences in responses for higher- and lower-cost products.

The survey addressed three primary research questions: (1) Do consumers notice the ''Product of USA'' label claim?; (2) Do consumers understand the current ''Product of USA'' definition and other ''USDA'' labeling (*e.g.,* ''USDA Choice'') as it relates to country of origin?; and (3) How much are consumers willing to pay for meat products bearing the ''Product of USA'' label claim for the current definition and potential revised definitions (*e.g.,* if the meat were from an animal that was born, raised, slaughtered, and processed in the United States)?

To investigate the first question, respondents completed a limited time exposure (LTE) task to determine whether consumers notice the ''Product of USA'' label claim (*i.e.,* to indicate saliency). Respondents were randomly assigned to view one of four mock products and were exposed to a mock product for a limited time (20 seconds), then asked to list what labeling features they recalled (unaided), and then asked to answer a series of recognition questions to indicate whether they saw specific images and phrases, including the ''Product of USA'' claim (*i.e.,* aided recognition questions). Results from the LTE's unaided recall questions show that 9 to 31 percent of participants correctly recalled seeing the ''Product of USA'' claim. Results from aided recognition questions show that 70 to 80 percent of participants correctly recalled seeing the ''Product of USA'' claim. The range in responses was dependent on the format of the claim. Results from the aided recognition questions also show

[18] Response to Petition 19–05 available at: *https://www.fsis.usda.gov/sites/default/files/media_file/2021-04/19-05-fsis-final-response-032620.pdf.*

[19] FSIS Petition 21–02, Petition for Notice and Comment Rulemaking on ''Product of USA'' Labels (June 10, 2021), available at: *https://www.fsis.usda.gov/sites/default/files/media_file/2021-06/21-02-NCBA-06102021.pdf.*

[20] Comments submitted for Petition 21–02 available at: *https://www.regulations.gov/document/FSIS-2021-0018-0001/comment.*

[21] 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.

[22] Selected panelists without internet access were provided with free internet access and a tablet computer, if needed.

that participants correctly recalled seeing the ''Product of USA'' label claim more often than other claims mentioned in the survey (*i.e.,* ''no antibiotics and no added hormones,'' an image of the USDA mark of inspection, ''100% grass fed,'' ''sustainably raised,'' ''eco-friendly,'' an image of the USDA organic seal, and ''certified humane raised and handled'').

To investigate the second question, respondents answered questions that surveyed their understanding of the meaning of ''Product of USA'' label claim as it relates to product country of origin (*e.g.,* born, raised, slaughtered, and processed). The survey asked the question, ''To your knowledge, what does the 'Product of USA' label claim on meat products mean?'' Four options with various combinations of ''born,'' ''raised,'' ''slaughtered,'' and ''processed'' in the United States were presented to participants. Of the responses, 47 percent of participants believed that the label indicates that the animal was born, raised, slaughtered, and the meat then processed, in the United States. Only 16 percent of participants selected the current meaning of the label claim (*i.e.,* the meat was processed in the United States.)

To investigate the third question, respondents were asked questions to measure their intrinsic value or willingness to pay (WTP) for products bearing the ''Product of USA'' label claim for the current definition and potential revised definitions. This approach captures the strength of preference (*i.e.,* potential price premium) for changes in attributes. Specifically, this approach helps FSIS determine which U.S. preparation and processing steps, if any, are valued by the average consumer. The results suggest that participants were willing to pay more for a product derived from animals when all preparation and processing steps occurred in the United States—born, raised, slaughtered, and processed—than for product when fewer steps occurred in the United States. FSIS has interpreted these results to access the value the average consumer derives from different definitions of ''Product of USA.''

The combined survey results suggest that consumers value ''Product of USA'' label claims, as understood by consumers as indicating U.S. born, raised, slaughtered, and processed, but that the current FSIS ''Product of USA'' label claim is misleading to a majority of consumers as to the actual origin of FSIS-regulated products. Based on the survey results, adopting the proposed definition of the ''Product of USA'' claim to mean the product was derived from an animal born, raised, slaughtered, and processed in the United States would enhance consumer purchasing decisions, result in truthful, less misleading ''Product of USA'' labels, and decrease false impressions about the origin of FSIS-regulated products in the marketplace. In particular, it would allow consumers to better comparison shop between products based on the value that consumers place on products fully raised and processed in the United States. Further discussion of survey results can be found in the benefits section of the Economic Impact Analysis of the proposed rule in Section IV.

III. Proposed Rule

In consideration of the petitions, the public comments submitted in response to the petitions, and the results of the Agency's 2022 consumer survey, FSIS has concluded that adherence to the current ''Product of USA'' labeling policy guidance may be leading to misleading labeling and causing confusion in the marketplace. The evidence reviewed by FSIS demonstrates that the current FSIS ''Product of USA'' labeling guidance does not conform to consumers' conception of what ''Product of USA'' claims mean on FSIS-regulated products. Therefore, the Agency is proposing 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 and processing, is of U.S. origin to ensure such labels do not mislead or confuse consumers. If finalized, the proposed requirements could affect the labeling of products that currently claim to be of U.S. origin but are prepared and processed from imported products shipped to the United States. For example, meat products derived from live animals that are imported into the United States for feeding or for immediate slaughter would no longer be allowed to bear the authorized claims ''Product of USA'' or ''Made in the USA.'' Similarly, imported meat products reprocessed in the United States would no longer be allowed to bear the authorized claims ''Product of USA'' or ''Made in the USA'', as currently allowed under the Food Standards and Labeling Policy Book. The proposed requirements would not affect the labeling of products exported to foreign countries. However, these products could still bear a qualified origin label claim, as discussed below, if all FSIS requirements, and foreign country requirements listed in the FSIS Export Library, have been met.

FSIS is proposing to amend its labeling regulations at 9 CFR part 412, Label Approval. Under the proposed provisions, the two authorized claims ''Product of USA'' and ''Made in the USA'' may be displayed on labels of FSIS-regulated products only if the product is derived from animals born, raised, slaughtered, and processed in the United States. FSIS is also proposing that claims other than the two authorized claims ''Product of USA'' and ''Made in the USA'' may be displayed on labels to indicate the U.S.-origin component of a product's preparation and processing. All U.S.-origin label claims that are not authorized claims are known as ''qualified claims.'' Qualified claims would need to include a description on the package of how the product compares to the regulatory criteria for the two authorized claims, ''Product of USA'' and ''Made in the USA,'' including all preparation and processing steps that occurred in the United States upon which the claim is made. For example, ''Sliced and packaged in the United States using imported pork'' could be a U.S.-origin qualified claim. FSIS is proposing that companies using a voluntary claim of U.S. origin on labels of FSIS-regulated products must, as with the use of all origin claims, maintain documentation to demonstrate that the product complies with criteria of the proposed regulatory requirements.

Scope of Allowed Claims

FSIS is proposing to allow two authorized voluntary label claims to indicate that a FSIS-regulated product is of U.S. origin: ''Product of USA'' and ''Made in the USA.'' The Agency is proposing to allow the use of these two authorized claims only if the labeled FSIS-regulated 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 components of the product are derived from animals born, raised, slaughtered, and processed in the United States; and (2) All additional ingredients of the product, other than spices and flavorings, are of domestic origin (*i.e.,* all preparation and processing steps of the ingredients are completed in the United States).

Label claims other than ''Product of USA'' or ''Made in the USA'' that indicate that a preparation and processing component of a FSIS-regulated product is of U.S. origin would be allowed (''qualified'' label claims), but such claims would need to

be positioned near a description on the package of how the product compares to the regulatory criteria for the two authorized claims, ''Product of USA'' and ''Made in the USA,'' including all preparation and processing steps that occurred in the United States upon which the claim is made. For example, a FSIS-regulated cured pork product package could include the qualified claim ''Sliced and packaged in the United States using imported pork.'' FSIS notes that in the case of the FSIS-regulated products that are also COOL covered commodities,[23] U.S.-origin label claims must comply with COOL requirements for the identification of country of origin, including production steps occurring in each country for commodities of multiple origins.[24]

FSIS requests comments on what criteria the Agency should establish for the use of qualified claims—claims that do not include ''Product of USA'' and ''Made in the USA''—to indicate that a preparation and processing component of a FSIS-regulated product is of U.S. origin.

U.S. State and Region Claims

Under the proposed rule, products labeled with voluntary authorized claims referring to the origin of a U.S. state or region (*e.g.,* ''Made in North Carolina'') would need to meet the proposed regulatory criteria for the two voluntary authorized claims ''Product of USA'' and ''Made in the USA'' (*i.e.,* born, raised, slaughtered, and processed in the state or region). Voluntary qualified claims referring to the state or region origin of a component of a FSIS-regulated product would need to include a description on the package of all preparation and processing steps that occurred in the state or region upon which the claim is made (*e.g.,* ''Packaged in Michigan.'') Currently, state and region 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 in which the product was prepared on the product label. Should the proposed rule become final, FSIS will issue revised labeling guidance on the use of voluntary authorized and qualified state and region claims.

Generic Approval of U.S.-Origin Claims

Under the proposed rule, both the two authorized claims ''Product of USA'' and ''Made in the USA'' and qualified claims of U.S. origin would continue to be eligible for generic approval under 9 CFR 412.2(a)(1). As with all generically approved labels, labels bearing U.S.-origin claims would be subject to routine IPP inspection tasks to verify that the labels comply with the regulatory criteria.

Scope of Products: Single Ingredient and Multi-Ingredient

The proposed rule would apply to all products subject to FSIS mandatory inspection or eligible for voluntary inspection services provided by the Agency. FSIS has proposed criteria for both single and multi-ingredient products to ensure that the claim is consistent for all FSIS-regulated products that use the ''Product of USA'' or ''Made in the USA'' claims. Single ingredient products bearing the authorized label claims ''Product of USA'' or ''Made in the USA'' would need to be derived from animals born, raised, slaughtered, and processed in the United States. Multi-ingredient products would be allowed to bear the authorized label claims ''Product of USA'' or ''Made in the USA'' if: (1) All FSIS-regulated components of the product are derived from animals born, raised, slaughtered, and processed in the United States; and (2) All additional ingredients, other than spices and flavorings, are of domestic origin (*i.e.,* all preparation and processing steps of the ingredients are completed in the United States). This proposed requirement for multi-ingredient products would align with the April 1985 FSIS policy memorandum, discussed above, that ''Product of USA'' labeling of a product would be misleading unless all the product's ingredients having a bearing on consumer preference are of domestic origin.

FSIS requests comments on whether the Agency should adopt an alternative requirement for multi-ingredient products that bear the authorized claims ''Product of USA'' or ''Made in the USA.''

FSIS Labeling and AMS Mandatory COOL

As discussed above, this proposed rule concerning voluntary U.S.-origin labeling for FSIS-regulated products does not conflict with AMS COOL requirements. Further, the proposed rule would not alter or affect any other federal statute or regulation relating to country of origin labeling 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.[25] Should this rule become final, any commodity that is subject to COOL mandatory country of origin labeling must continue to comply with those requirements.

Required Documentation To Support Claims

Official establishments and facilities choosing to use an authorized or qualified U.S.-origin claim on labels of FSIS-regulated products would need to maintain documentation to demonstrate that the product complies with criteria of the proposed regulatory requirements, and that the claim is not false or misleading, as the regulations require for the use of all generically approved labels (9 CFR 412.2(a)(1)). FSIS would accept existing documentation to demonstrate compliance with one or more of the proposed regulatory requirements. For example, an establishment or facility seeking to use a voluntary claim of U.S. origin may already maintain supplier sheets from the farm that raised a source animal as part of its labeling recordkeeping pursuant to existing FSIS regulations or participation in another federal program (*e.g.,* AMS COOL). 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, is of U.S. origin.

- Labels that bear the voluntary authorized claims ''Product of USA'' or ''Made in the USA'' under the proposed new regulatory 9 CFR 412.3(a) and (b) may have:
  - A written description of the controls used in the birthing, raising, slaughter, and processing of the source animals, and for multi-ingredient products the preparation and processing of all additional ingredients other than spices and flavorings, to ensure that each step complies with the proposed regulatory criteria;
  - A written description of the controls used to trace and segregate,

[23] The FSIS-regulated products that are also COOL covered commodities are ground and muscle cuts of lamb, chicken and goat (7 CFR 65.135) and Siluriformes fish (7 CFR 60.106). COOL covered commodities meeting the regulatory definition of ''processed food item(s)'' are exempted from mandatory country of origin labeling (7 CFR 60.119 and 7 CFR 65.220).

[24] 7 CFR 60.200 and 7 CFR 65.300.

[25] 9 CFR 317.8(b)(40). 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 60.300(a) and 65.400(a)).

from the time of birth or processing through packaging and wholesale or retail distribution, source animals, all additional ingredients other than spices and flavorings, and resulting products that comply with the proposed 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.

• Labels that bear voluntary, qualified U.S.-origin claims under the proposed new regulatory 9 CFR 412.3(c) may have:

○ A written description of the controls used in each applicable preparation and processing step of source animals, all additional ingredients other than spices and flavorings, and resulting products to ensure that the U.S.-origin claim complies with the proposed regulatory criteria. The described controls may include those used to trace and segregate, during each applicable preparation or processing step, source animals, 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 qualified U.S.-origin claim regarding the source of the preparation and processing component is not false or misleading.

The proposed rule does not specify the types of documentation that must be maintained to demonstrate compliance with the proposed regulatory criteria (*e.g.,* bills of lading, shipping manifests, load sheets, grower records). Should the rule become final, FSIS would issue guidance, as needed, on recommended documentation to maintain compliance with U.S.-origin labeling requirements.[26] FSIS requests comments on whether the Agency should require, or provide guidance on, specific types of documentation that companies using a voluntary label claim of U.S. origin would need to maintain to demonstrate that the product complies with criteria of the proposed regulatory requirements. Further, FSIS requests comments on whether the Agency should allow or require third party certification for the use of authorized and qualified voluntary U.S.-origin label claims.

Compliance Date and Transition Period

Generally, FSIS uses a uniform compliance date for new labeling regulations.[27] Should the proposed rule become final, on the applicable compliance date, FSIS would consider as compliant only labels bearing the two authorized claims ''Product of USA'' and ''Made in the USA'' for FSIS-regulated products that comply with the proposed codified definition for this claim. Also on the applicable compliance date, FSIS would consider as compliant only labels bearing qualified claims of U.S. origin for FSIS-regulated products that comply with the proposed codified requirements for the use of such claims.

IV. Executive Orders 12866 and 13563

Executive Orders (E.O.) 12866 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 proposed rule has been designated an ''economically significant'' regulatory action by the Office of Information and Regulatory Affairs under section 3(f)(1) of E.O. 12866. Accordingly, the proposed rule has been reviewed by the Office of Management and Budget under E.O. 12866.

A. Economic Impact Analysis

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.[28] For instance, currently, the beef in a package of ground beef can come from the U.S., from another country or countries, or from both depending on where each step of the preparation of the beef takes place, and still bear the claim ''Product of USA'' even if the ground beef is merely processed in the United States. Similarly, 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 USDA 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 a consumer web-based survey [29] to gather information on the American consumers' understanding of the meaning of the ''Product of USA'' claim. Based on the evidence reviewed by FSIS, FSIS has concluded that the current ''Product of USA'' labeling policy guidance may not reflect consumers' common understanding of what ''Product of USA'' claims mean on FSIS-regulated products. Therefore, the Agency is proposing 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

If finalized, the proposed changes 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 requests comments on how such a change may impact an establishment's cost. FSIS used Label Insight [30] 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.[31]

[26] For an example of current FSIS guidance on documentation typically needed to support label claims, see *Food Safety and Inspection Service Labeling Guideline on Documentation Needed to Substantiate Animal Raising Claims for Label Submission* (December 2019), available at: *https://www.fsis.usda.gov/guidelines/2019-0009.*

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

[28] 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* (Accessed on January 31, 2023).

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

[30] 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.

[31] 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.

This analysis identified two types of U.S.-origin claims: (1) Authorized claims, *e.g.,* ''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.[32] 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.[33]

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 Proposed Action

The proposed rule is expected to result in quantified industry relabeling, recordkeeping, and market testing costs, which combined are estimated to cost $3 million, annualized at a 7 percent discount rate over 10 years. Details of these cost estimates are provided below. There is the potential that this analysis has not captured all of the relevant costs associated with this proposed rule, such as costs from voluntary changes in production practices. The Agency is seeking comment on any such omitted costs.

Relabeling Costs

Under this proposed rule, FSIS-regulated single ingredient and multi-ingredient products that are not derived from animals born, raised, slaughtered, and processed in the United States would no longer be able to bear the authorized claims of ''Product of USA'' or ''Made in the USA.'' These products would have to be relabeled by either removing the authorized voluntary claim or using another claim, such as a qualified claim. For example, a FSIS-regulated cured meat 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 would no longer meet the proposed requirements for using their existing labels, this analysis utilized the 2014 Food and Drug Administration (FDA) Label Cost Model (FDA Label Cost Model) [34] 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 would modify or remove the claim in response to this proposed rule as some labels already meet the proposed and current labeling criteria. However, it is difficult to estimate the number of claims that would change if the proposed rule is finalized, 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. FSIS requests comments on these assumptions, including whether the prevalence of label change would differ depending on whether existing label claims are Authorized or Qualified.

TABLE 2—NUMBER OF FSIS LABELS THAT WOULD 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

[32] 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.

[33] 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.

[34] 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 2—NUMBER OF FSIS LABELS THAT WOULD BE RELABELED—Continued

Estimate	Labels with U.S.-origin claims	Count of labels with changes
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 a final rule. FSIS anticipates the compliance period would be somewhere between 12 and 36 months. Assuming a 24-month compliance period, 100 percent of branded products label updates would be coordinated with a planned label change. However, for private (store brand) labels, only 26 percent would have a coordinated label change, and 74 percent would be uncoordinated.[35] 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.[36] Therefore, an estimated 81.5 percent of the labels requiring an update as a result of the rule would have a coordinated change and 18.5 percent would have an uncoordinated change.[37] Based on the FDA Label Cost Model, the label changes that would result from the rule are considered minor. We are asking for comment on whether some of these changes should be major label changes. 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.[38]

TABLE 3—TOTAL NUMBER OF FSIS LABELS THAT WOULD 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 2021 producer price indices for the material and consultation costs and 2021 wage rates [39] for the labor hours. The cost estimates in 2021 U.S. dollars are: $848 per label for a minor coordinated change (with a range of $205 to $1,797), and $4,829 per label for a minor uncoordinated change (with a range of $2,142 to $8,738). Combined, the mean estimated relabeling cost is $1.2 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	$13.9
Uncoordinated	Minor	1.0	5.1	15.3
Total Cost∧[1]		1.5	9.1	29.2
Annualized Cost (3% DR, 10 Year)		0.2	1.0	3.3
Annualized Cost (7% DR, 10 Year)		0.2	1.2	3.9

[1] Totals may not sum due to rounding.

Recordkeeping Costs

Currently, businesses using labels to designate the U.S.-origin production or preparation component of a product must maintain records to support the U.S.-origin claim.[40] 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.[41] FSIS estimated that the provisions in this proposed rule, if finalized, would require businesses to spend an additional 20 minutes to gather their

[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. Table 3–1. Assumed Percentages of Changes to Branded and Private-Label UPCs that Cannot be Coordinated with a Planned Change.

[36] 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.*

[37] 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.

[38] 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.

[39] 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.

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

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

records, 20 times per year, per respondent. FSIS acknowledges that it would 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 could elect to either remove the U.S. origin claim from the label or make an alternative claim. FSIS requests comments on how such a change may impact an establishment's cost and benefits. 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 would have additional recordkeeping costs if the proposed rule were finalized. This analysis assumed this recordkeeping would be completed by an operations manager with an hourly estimated cost of $98.50 at the median and a range of wages from ($71.84 to $154.78).[42] As such, the estimated annual cost per business is approximately $656. The estimated annual cost to all 1,575 businesses is approximately $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	$1.0	$1.6
Annualized Cost (3% DR, 10 Year)			0.8	1.0	1.6
Annualized Cost (7% DR, 10 Year)			0.8	1.0	1.6

Market Testing

To assess the marketability of potential label changes, the FDA Label Cost Model includes information on five types of market tests:[43] focus group, discrimination test, central location test, descriptive test, and in-home test. The mean cost for these market tests ranges from $7,211 to $36,570 per formula.[44] The FDA Label Cost Model reports that minor label changes are unlikely to incur any market testing costs.[45] However, if this proposed rule were to finalize, some businesses may still want to conduct market testing to assess how consumers would respond to a label change. FSIS estimates that 25 to 75 percent of businesses that have products with U.S.-origin claims would conduct a focus group test on one product formula. FSIS assumed that not every brand would conduct market testing because not every brand would 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 $7,440 per formula (with a range of $7,048 to $7,831) in 2021 dollars.[46] Combined, the mean estimated market testing cost is $0.8 million, annualized at a 7 percent discount rate over 10 years, table 6. The Agency is seeking comment on the assumptions used for the market testing costs.

TABLE 6—MARKET TESTING COSTS IN MILLIONS OF DOLLARS

	Lower	Mean	Upper
Total Businesses with Market Testing	394	788	1,181
Total Cost [1]	$2.8	$5.9	$9.2
Annualized Cost (3% DR, 10 Year)	$0.3	$0.7	$1.0
Annualized Cost (7% DR, 10 Year)	$0.4	$0.8	$1.2

[1] Totals may not sum due to rounding.

Cost Summary

Under the provisions in this proposed rule, if finalized, industry would likely incur a one-time relabeling cost and annual recordkeeping costs. Combined and annualized assuming a 7 percent discount rate over 10 years, total industry cost is $3.0 million, table 7.

[42] The hourly cost includes a wage rate of $49.25 and a benefits and overhead factor of 2. Estimates obtained from the Bureau of Labor Statistics May 2021, National Industry-Specific Occupational Employment and Wage Estimates, for Management Occupations 50th (25th–75th percentile) (Occupational Code 11–0000), Management Occupations (*bls.gov*).

[43] Mean estimates from the 2014 FDA Label Cost Model were updated to 2021 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).

[44] 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.

[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 4–32. For minor labeling changes, ATC [analytical testing costs] and MTC [market testing costs] are likely to be 0.

[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. Page 4–43.

TABLE 7—TOTAL COSTS IN MILLIONS OF DOLLARS

Cost type	Lower	Mean	Upper
Relabeling	$1.5	$9.1	$29.2
Recordkeeping	0.8	1.0	1.6
Market Testing	2.8	5.9	9.2
Annualized Cost (3% DR, 10 Year)	1.3	2.7	5.9
Annualized Cost (7% DR, 10 Year)	1.4	3.0	6.7

Totals may not sum due to rounding.

Expected Benefit of the Proposed 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 suggests that the current ''Product of USA'' label claim is misleading to a majority of consumers. This proposed rule would adopt a requirement for the ''Product of USA'' claim that would 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

Numbers 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' willingness to pay (WTP) for different U.S.-origin claims using two discrete choice experiments (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 WTP 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 marginal WTP for products that were born, raised, slaughtered, and processed in the United States, table 9. Specifically, results show a marginal WTP 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—MARGINAL WTP 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 WTP 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 [47] 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 [48] 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 would 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 and is seeking comment on this assumption.

This data from the RTI survey and implicit price premium analysis suggests that a false or misleading ''Product of USA'' claim would economically harm consumers, who look to such labeling to convey accurate information about the U.S. origin of the production and preparation of the labeled product consistent with consumers' understanding of what that label means to them. 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 proposed ''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 proposed changes to the ''Product of USA'' voluntary labeling policy are intended to reduce false or misleading U.S. origin labeling (See 9 CFR 317.8(a)), 381.129(b), 590.411(f)(1)).[49] This would reduce the market failures associated with incorrect and imperfect information. The proposed changes would benefit consumers by matching the voluntary authorized ''Product of USA'' and ''Made in the USA'' label claims with the definition that consumers' likely expected, *i.e.,* as product being derived from animals born, raised, slaughtered, and processed in the United States.

The benefits for this proposed rule have not been quantified due to data, including the divergence between estimated values and what would be changed by the proposed rule, and the limitations (some of which are discussed in Appendix A) associated with the associated surveys, LTE experiments, DCEs, and hedonic price modeling. However, if finalized, the proposed changes would allow consumers to make informed purchasing decisions, resulting in an increase in consumer benefit and preventing market distortions. We request comments on the potential consumer and industry benefits of the proposed rule.

Alternative Regulatory Approaches

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

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

[47] 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.*

[48] 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.''

[49] 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

Alternative	Benefits	Cost
1—No Action	No benefit. Misinformation remains	No relabeling costs or increase in recordkeeping costs.
2—The Proposed Rule	More accurate information conveyed on labels with U.S-origin claims.	$3 million total costs. Relabeling cost $1.2 million. Recordkeeping cost $1.0 million. Market testing cost $0.8 million.
3—Extended Compliance Period.	Reduced benefits because labels with U.S.-origin claims would change at a slower rate and potentially include information that may mislead consumers for an extended period.	$2.5 million total costs. Relabeling cost $0.6 million. Recordkeeping cost $1.0 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 will be worse off absent the proposed action. While ''no action'' means the manufacturers currently labeling their products with U.S.-origin claims do not have to relabel or increase record-keeping 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 Proposed Rule

Under this proposed 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 on the package of how the product compares to the regulatory ''Product of USA'' and ''Made in the USA'' definition, including all preparation and processing steps that occurred in the United States upon which the claim is made (as described above). Consumers would benefit from the proposed 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 Proposed 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 $0.5 million, as compared to assuming a 24-month compliance period. Recordkeeping and market testing costs would remain the same as alternative 2.

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 proposed 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. 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	$4.9	$17.0
Recordkeeping, Recurring	0.8	1.0	1.6
Market Testing, One-time	2.8	5.9	9.2
Annualized Cost (3% DR, 10 Year)	1.1	2.3	4.6
Annualized Cost (7% DR, 10 Year)	1.2	2.5	5.1

Regulatory Flexibility Act Assessment

The FSIS Administrator has made a preliminary determination that this proposed rule, if finalized, would not have a significant economic impact on a substantial number of small entities in the U.S., as defined by the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).[50]

FSIS used brand names found in Label Insight data as a proxy for businesses. Although Label Insight does not have company or size information associated with the Universal Product Codes (UPCs), Label Insight does include brand names for labels. FSIS assumed brands with fewer than 50 UPCs associated with FSIS-regulated products were small businesses.

FSIS estimated that the proposed rule would impact 1,349 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 requests comments on the

[50] Small Businesses are based on the United States Small Business Administration (SBA) size standards. The SBA 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. A business in 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 standard.

United States Small Business Administration (SBA), Table of Small Business Standards Matched to North American Industry Classification System Codes. Effective February 26, 2016. Available at *https://www.sba.gov/sites/default/files/files/Size_Standards_Table.pdf.*

number of small businesses affected and potential impact.

FSIS estimated that between 1,000 and 3,000 labels from small business may need changes if the proposed rule is finalized, assuming 25, 50, and 75 percent of labels would need to be changed. The average one-time cost estimate for minor label changes is between $848 and $4,829 per label. The expected one-time relabeling cost for 81.5 percent of labels are for minor coordinated changes and are approximately $848 per label. The expected one-time relabeling cost for 18.5 percent of labels are for minor uncoordinated changes, at approximately $4,829 per label.[51]

In addition, businesses would have increased recordkeeping costs. This analysis assumed this recordkeeping would be completed by an operations manager with an estimated hourly cost of $98.50 at the median and a range of wages from ($71.84 to $154.78) for 20 minutes, 20 times per year (please see recordkeeping section above for more information).[52]

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 if the proposed rule is finalized, assuming 25, 50, and 75 percent of the 1,349 small businesses conduct market testing. The expected mid-point one-time market testing costs for those small businesses that choose to conduct market testing is $7,440 in 2021 dollars.

The total mid-point cost estimate is $1.9 million, which is roughly $1,408 per small business ($1.9M/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.

TABLE 12—TOTAL SMALL BUSINESS COSTS, IN MILLIONS OF DOLLARS

Cost type	Lower	Mean	Upper
Relabeling, One-time	$0.6	$3.2	$9.2
Recordkeeping, Recurring	0.6	0.9	1.4
Market Testing, One-time	2.0	4.3	6.8
Annualized Cost (3% DR, 10 Year)	0.9	1.8	3.3
Annualized Cost (7% DR, 10 Year)	1.0	1.9	3.5

V. Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995, the information collection or recordkeeping requirements included in this proposed rule have been submitted for approval to OMB.

Title: Product of USA.

OMB Number: 0583–NEW.

Type of Request: Request for a new information collection.

Abstract: FSIS has been delegated the authority to exercise the functions of the Secretary (7 CFR 2.18, 2.53) as specified in the Federal Meat Inspection Act (FMIA) (21 U.S.C. 601, *et seq.*), the Poultry Products Inspection Act (PPIA) (21 U.S.C. 451, *et seq.*), and the Egg Products Inspection Act (EPIA) (21 U.S.C. 1031, *et seq.*). These statutes mandate that FSIS protect the public by verifying that meat, poultry, and egg products are safe, wholesome, and properly labeled and packaged.

FSIS is proposing to amend its regulations to define the conditions under which the labeling of FSIS-regulated products may bear voluntary claims indicating that the product is of United States origin. Under the recordkeeping requirements associated with generically approved labeling, records must be maintained to demonstrate compliance with proposed regulatory requirements for labels bearing U.S.-origin claims.[53]

At the final rule stage, FSIS intends to merge this information collection with the existing information collection titled *Marking, Labeling, and Packaging of Meat, Poultry, and Egg Products* (0583–0092). Under the recordkeeping requirements associated with generically approved labeling, FSIS estimates that it will take an additional 20 minutes to comply with ''Product of USA'' label recordkeeping requirements, 20 times annually. FSIS has made the following estimates based upon an information collection assessment:

Respondents: Official domestic establishments.

Estimated total number of respondents: 1,575.

Estimated annual number of responses per respondent: 20.

Estimated total annual burden on respondents: 10,500 hours.

All responses to this notice will be summarized and included in the request for OMB approval. All comments will also become a matter of public record. Copies of this information collection assessment can be obtained from Gina Kouba, Office of Policy and Program Development, Food Safety and Inspection Service, USDA, 1400 Independence Avenue SW, Mailstop 3758, South Building, Washington, DC 20250–3700; (202) 937–4272.

Comments are invited on: (a) whether the proposed collection of information is necessary for the proper performance of FSIS' functions, including whether the information will have practical utility; (b) the accuracy of FSIS' estimate of the burden of the proposed collection of information, including the validity of

[51] Mean estimates from the 2014 FDA Label Cost Model were updated to 2021 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.

[52] The hourly cost includes a wage rate of $49.25 and a benefits and overhead factor of 2. Estimates obtained from the Bureau of Labor Statistics May 2021, National Industry-Specific Occupational Employment and Wage Estimates, for Management Occupations 50th (25th–75th percentile) (Occupational Code 11–0000), Management Occupations (*bls.gov*).

[53] As discussed above (see Section III. Proposed Rule, Required Documentation to Support Claims), under the proposed rule, labels that bear the voluntary authorized claims ''Product of USA'' or ''Made in the USA'' may have: (1) A written description of the controls used in the birthing, raising, slaughter, and processing of the source animals, 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 the proposed regulatory criteria; (2) A written description of the controls used to trace and segregate source animals, all additional ingredients other than spices and flavorings, and resulting products that comply with the proposed regulatory criteria from those that do not comply; or (3) A signed and dated document describing how the product is prepared and processed to support that the claim is not false or misleading. Under the proposed rule, labels that bear voluntary qualified U.S.-origin claims may have: (1) A written description of the controls used in each applicable step of source animals, all additional ingredients other than spices and flavorings, and resulting products to ensure that the U.S.-origin claim complies with the proposed regulatory criteria; or (2) A signed and dated document describing how the qualified U.S.-origin claim regarding the source of the preparation and processing component is not false or misleading.

the method and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques, or other forms of information technology. Comments may be sent to both FSIS, at the addresses provided above, and the Desk Officer for Agriculture, Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Washington, DC 20253.

VI. 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.

VII. Executive Order 12988, Civil Justice Reform

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

VIII. Executive Order 13175

This proposed 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 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 proposed rule on Indian tribes and determined that this proposed 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.

IX. 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.

X. 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 proposed rule, which would 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(b)(6) of the U.S. Department of Agriculture regulations.

XI. 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.

XII. Proposed Rule Text

List of Subjects in 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 proposing to amend 9 CFR part 412 as follows:

PART 412—LABEL APPROVAL

■ 1. 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.

■ 2. Add § 412.3 to read as follows:

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

(a) The authorized 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) The authorized claims ''Product of USA'' and ''Made in the USA'' may be used under generic approval on labels to designate multi-ingredient products if all FSIS-regulated components of the product are derived from animals born, raised, slaughtered, and processed in the United States, and all other ingredients in the product are of domestic origin. 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 only if the product also includes a description on the package as to how the claim compares to the definitions for the authorized claims, ''Product of USA'' and ''Made in the USA'' as set forth in paragraphs (a) and (b) of this section. The product must include a description on the package of all 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.

(1) The wording of the package description must be shown in print no smaller than one third the size of the largest letter in the U.S.-origin claim, and positioned near the U.S.-origin claim.

(d) In addition to the requirements in § 412.2, official establishments using and facilities choosing to use labels that bear the authorized 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 authorized 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 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 segregate, from the time of birth or processing through packaging and wholesale or retail distribution, source animals, all additional ingredients other than spices and flavorings, and resulting products that comply with paragraphs (a) and (b) of this section from those that do not comply.

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

(e) In addition to the requirements in § 412.2, official establishments using and facilities choosing to use a qualified U.S.-origin label claim to designate the U.S.-origin preparation and processing component 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, all additional ingredients other than spices and flavorings, and resulting products to demonstrate that the qualified U.S.-origin claim complies with paragraph (c) of this section. The described controls may include those used to trace and segregate, during each applicable step, source animals, 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 component is not false or misleading.

Done in Washington, DC.

Paul Kiecker,

Administrator.

[FR Doc. 2023–04815 Filed 3–10–23; 8:45 am]

BILLING CODE 3410–DM–P

FEDERAL HOUSING FINANCE AGENCY

12 CFR Part 1240

RIN 2590–AB27

Enterprise Regulatory Capital Framework—Commingled Securities, Multifamily Government Subsidy, Derivatives, and Other Enhancements

AGENCY: Federal Housing Finance Agency.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Federal Housing Finance Agency (FHFA or the Agency) is seeking comments on a notice of proposed rulemaking (proposed rule) that would amend several provisions in the Enterprise Regulatory Capital Framework (ERCF) for the Federal National Mortgage Association (Fannie Mae) and the Federal Home Loan Mortgage Corporation (Freddie Mac, and with Fannie Mae, each an Enterprise). The proposed rule would include modifications related to guarantees on commingled securities, multifamily mortgage exposures secured by government-subsidized properties, derivatives and cleared transactions, and credit scores, among other items.

DATES: Comments must be received on or before May 12, 2023.

ADDRESSES: You may submit your comments on the proposed rule, identified by regulatory information number (RIN) 2590–AB27, by any one of the following methods:

- *Agency website: www.fhfa.gov/open-for-comment-or-input.*
- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. If you submit your comment to the Federal eRulemaking Portal, please also send it by email to FHFA at *RegComments@fhfa.gov* to ensure timely receipt by FHFA. Include the following information in the subject line of your submission: Comments/RIN 2590–AB27.
- *Hand Delivered/Courier:* The hand delivery address is: Clinton Jones, General Counsel, Attention: Comments/RIN 2590–AB27, Federal Housing Finance Agency, 400 Seventh Street SW, Washington, DC 20219. Deliver the package at the Seventh Street entrance Guard Desk, First Floor, on business days between 9 a.m. and 5 p.m.