information directly to the manager of the certification office, send it to the attention of the person identified in Related Information. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the responsible Flight Standards Office.

(j) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Civil Aviation Authority of Israel (CAAI) Israeli AD ISR–I–24–2021–6–6R1, dated June 27, 2021, for related information. This MCAI may be found in the AD docket on the internet at *https://www.regulations.gov* by searching for and locating Docket No. FAA–2021–0566.

(2) For more information about this AD, contact Brian Hernandez, Aerospace Engineer, Systems and Equipment Section, FAA, Seattle ACO Branch, 2200 South 216th St., Des Moines, WA 98198; phone and fax: 206–231–3535; email: *Brian.Hernandez@faa.gov.*

(k) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(i) IAI-Aviation Group Alert Service Bulletin 368–24–098, Revision 1, dated June 2021.

(ii) [Reserved]

(3) For service information identified in this AD, contact Israel Aerospace Industries, Ltd., Ben Gurion Airport, Israel 70100; telephone 972–39359826; email *tmazor@iai.co.il.*

(4) You may view this service information at the FAA, Airworthiness Products Section, Operational Safety Branch, 2200 South 216th St., Des Moines, WA. For information on the availability of this material at the FAA, call 206–231–3195.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, email *fedreg.legal@nara.gov,* or go to: *https://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued on July 8, 2021.

Gaetano A. Sciortino,

Deputy Director for Strategic Initiatives, Compliance & Airworthiness Division, Aircraft Certification Service.

[FR Doc. 2021–15026 Filed 7–12–21; 11:15 am]

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FEDERAL TRADE COMMISSION

16 CFR Part 323

[3084–AB64]

Made in USA Labeling Rule

AGENCY: Federal Trade Commission.

ACTION: Final rule.

SUMMARY: The Federal Trade Commission (''FTC'' or ''Commission'') issues a final rule related to ''Made in USA'' and other unqualified U.S.-origin claims on product labels.

DATES: This final rule is effective August 13, 2021.

FOR FURTHER INFORMATION CONTACT: Julia Solomon Ensor (202–326–2377) or Hampton Newsome (202–326–2889), Attorneys, Division of Enforcement, Bureau of Consumer Protection, Federal Trade Commission, Room CC–9528, 600 Pennsylvania Avenue NW, Washington, DC 20580.

SUPPLEMENTARY INFORMATION:

I. Background

On July 16, 2020, the Commission published a Notice of Proposed Rulemaking (''NPRM'') (85 FR 43162) seeking comments on a new rule regarding unqualified U.S.-origin claims (''MUSA claims'') on product labels. The NPRM was preceded by a review of the Commission's longstanding program to prevent deceptive MUSA claims.[1] The review included a 2019 public workshop and public comment period, where stakeholders expressed nearly universal support for a rule addressing MUSA labels.[2]

The Commission published a new rule in the NPRM pursuant to its authority under 15 U.S.C. 45a (''Section 45a''). Section 45a declares: ''[t]o the extent any person introduces, delivers for introduction, sells, advertises, or offers for sale in commerce a product with a 'Made in the U.S.A.' or 'Made in America' label, or the equivalent thereof, in order to represent that such product was in whole or substantial part of domestic origin, such label shall be consistent with decisions and orders of the Federal Trade Commission.'' The statute authorizes the agency to issue rules to effectuate this mandate and prevent unfair or deceptive acts or practices relating to MUSA labeling.[3] Specifically, under the statute, the Commission ''may from time to time issue rules pursuant to section 553 of title 5, United States Code'' requiring MUSA labeling to ''be consistent with decisions and orders of the Federal Trade Commission issued pursuant to [Section 5 of the FTC Act].'' The statute authorizes the FTC to seek civil penalties for violations of such rules.[4]

Consistent with these statutory provisions, the NPRM proposed a rule covering labels on products that make unqualified U.S.-origin claims. Consistent with the Commission's MUSA Decisions and Orders since the 1940s,[5] the NPRM proposed to codify the established principle that unqualified U.S.-origin claims imply to consumers no more than a *de minimis* amount of the product is of foreign origin.[6]

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[1] This program consisted of compliance monitoring, counseling, and targeted enforcement pursuant to the FTC's general authority under 15 U.S.C. 45 (''Section 5'' of the FTC Act). Section 5 prohibits unfair or deceptive acts or practices in or affecting commerce. An act or practice is deceptive if it is likely to mislead consumers acting reasonably under the circumstances and is material—that is, likely to affect a consumer's decision to purchase or use the advertised product or service. A claim need not mislead all—or even most—consumers to be deceptive under the FTC Act. Rather, it need only be likely to deceive some consumers acting reasonably. *See FTC Policy Statement on Deception,* 103 F.T.C. 174 (1984) (*appended to Cliffdale Assocs., Inc.,* 103 F.T.C. 110, 177 n.20 (1984) (''A material practice that misleads a significant minority of reasonable consumers is deceptive.''); *see also FTC* v. *Stefanchik,* 559 F.3d 924, 929 (9th Cir. 2009) (''The FTC was not required to show that all consumers were deceived . . . .'').

[2] Commenters argued such a rule could have a strong deterrent effect against unlawful MUSA claims without imposing new burdens on law-abiding companies. *See generally* Transcript of Made in USA: An FTC Workshop (Sept. 26, 2019) at 63–72, *available at https://www.ftc.gov/news-events/events-calendar/made-usa-ftc-workshop;* FTC Staff Report, Made in USA Workshop (June 2020) (''MUSA Report''), *available at https://www.ftc.gov/system/files/documents/reports/made-usa-ftc-workshop/p074204_-_musa_workshop_report_-_final.pdf.*

[3] *See* Section 320933 of the Violent Crime and Law Enforcement Act of 1994, Public Law 103–322, 108 Stat. 1796, 2135, codified in relevant part at 15 U.S.C. 45a. Section 45a also states: ''This section shall be effective upon publication in the **Federal Register** of a Notice of the provisions of this section.'' The Commission published such a notice in 1995 (60 FR 13158 (Mar. 10, 1995).

[4] Under the statute, violations of any rule promulgated pursuant to Section 45a ''shall be treated by the Commission as a violation of a rule under section 57a of this title regarding unfair or deceptive acts or practices.'' For violations of rules issued pursuant to 15 U.S.C. 57a, the Commission may commence civil actions to recover civil penalties. *See* 15 U.S.C. 45(m)(1)(A).

[5] *See, e.g., Vulcan Lamp Works, Inc.,* 32 F.T.C. 7 (1940); *Windsor Pen Corp.,* 64 F.T.C. 454 (1964) (articulating this standard as a ''wholly of domestic origin'' standard).

[6] This principle was incorporated into the Commission's 1997 *Enforcement Policy Statement on U.S. Origin Claims* (the ''Policy Statement'') following consumer research and public comment, as the ''all or virtually all'' principle. Specifically, the Policy Statement provides a marketer making an unqualified claim for its product should, at the time of the representation, have a reasonable basis for asserting ''all or virtually all'' of the product is made in the United States. FTC, *Issuance of Enforcement Policy Statement on ''Made in USA'' and Other U.S. Origin Claims,* 62 FR 63756, 63766

The NPRM, consistent with the Commission's prior rulings and consumer perception surveys, proposed a rule prohibiting marketers from including unqualified U.S.-origin claims on labels unless: (1) Final assembly or processing of the product occurs in the United States; (2) all significant processing for the product occurs in the United States; and (3) all or virtually all of the product's ingredients or components are made and sourced in the United States. By codifying existing guidance, the proposed rule sought to impose no new obligations on market participants.

To avoid confusion or perceived conflict with other country-of-origin labeling laws and regulations, the NPRM contained a provision specifying the rule does not supersede, alter, or affect any other federal or state statute or regulation relating to country-of-origin labels, except to the extent a state country-of-origin statute, regulation, order, or interpretation is inconsistent with the proposed rule.[7]

In response to the NPRM, the Commission received hundreds of comments, discussed *infra* Section II. Although some raised concerns or recommended changes to the Commission's proposal, the majority supported finalizing the rule as drafted. Accordingly, the Commission adopts the proposed rule with limited modifications as discussed below.[8] The rule will take effect August 13, 2021.

II. Response to Comments

The Commission received more than 700 comments[9] in response to the NPRM from individuals, industry groups, consumer organizations, and members of Congress. Commenters generally supported the rule,[10] stating it provided much-needed clarity[11] and would deter bad actors[12] without imposing new burdens on marketers.[13] Most commenters agreed the rule should incorporate the longstanding ''all or virtually all'' standard.[14] Additionally, the majority of commenters addressing the issue agreed the proposed rule represented a proper exercise of the Commission's rulemaking authority under Section 45a.

Although the Commission received mostly supportive comments, some commenters raised concerns with the Commission's proposal to codify the ''all or virtually all'' guidance through rulemaking, suggesting the standard may not reflect current consumer perception. Others proposed specific additions to the rule, including additional definitions, guidance on implied claims, and an effective date. Members of the beef and shrimp industries requested specific guidance for their industries. A few stakeholders proposed changes outside the scope of the FTC's Section 45a rulemaking authority. For example, some commenters proposed making country-of-origin labeling mandatory in all instances. Finally, some raised miscellaneous concerns about particular businesses' practices or claims.[15] As discussed below, these comments do not provide a compelling basis to change the substantive requirements of the rule proposed in the NPRM.

A. Rulemaking Authority Regarding Mail Order Advertising

Eleven stakeholders filed comments addressing the FTC's rulemaking authority under Section 45a, with the majority agreeing the proposed rule is consistent with that grant of authority.[16] As described in Section I, Section 45a authorizes the Commission ''[to] issue rules pursuant to section 553 of title 5 [of the U.S.C.]'' to govern the use of '' 'Made in the U.S.A.' or 'Made in America' label[s], or the equivalent thereof'' when a person ''introduces, delivers for introduction, sells, advertises, or offers for sale [a product] in commerce.'' The statute provides such labels must be ''consistent with decisions and orders of the Federal Trade Commission issued pursuant to [Section 5 of the FTC Act].''[17]

1. Comments

Eleven commenters addressed the Commission's authority under Section 45a. The majority asserted the proposed rule was within the scope of Section 45a's grant of rulemaking authority, and the proposed rule appropriately covered labels in mail order (electronic) advertising.[18] For example, *TINA.org* argued the Commission properly interpreted Section 45a as authorizing coverage of electronic labels because Section 45a does not limit the term ''labels'' to physical labels, and physical and digital labels are ''functionally equivalent'' in terms of providing product information to consumers.[19] *TINA.org* further noted ''[w]hen Congress seeks to limit 'labels' to the physical, it knows how . . . [and here] the statute makes no attempt to restrict the definition or distinguish physical labels from digital labels.''[20] Moreover, *TINA.org* explained, limiting the proposed rule to physical labels without addressing electronic labels

(Dec. 2, 1997). The Commission first used the ''all or virtually all'' language in *Hyde Athletic Industries,* File No. 922–3236 (consent agreement accepted subject to public comment Sept. 20, 1994) and *New Balance Athletic Shoes, Inc.,* Docket 9268 (complaint issued Sept. 20, 1994). In the 1997 **Federal Register** Notice requesting public comment on Proposed Guides for the Use of U.S. Origin Claims, the Commission explained the ''all or virtually all'' standard merely rearticulated longstanding principles governing MUSA claims. FTC, *Request for Public Comment on Proposed Guides for the use of U.S. Origin Claims,* 62 FR 25020 (May 7, 1997). The Commission has routinely applied this standard in its MUSA Decisions and Orders since 1997. *See* Compilation of cases at *https://www.ftc.gov/tips-advice/business-center/legal-resources?type=case&field_consumer_protection_topics_tid=234.*

[7] *See, e.g.,* Textile Fiber Products Identification Act (15 U.S.C. 70b); Wool Products Labeling Act (15 U.S.C. 68); American Automobile Labeling Act (49 U.S.C. 32304); Agricultural Marketing Act (7 U.S.C. 1638a); Buy American Act (41 U.S.C. 10a–10c); and implementing rules.

[8] As discussed in Section III of this Notice, the Commission has added a provision (section 323.6) in the final Rule related to petitions for exemption.

[9] Comments appear on FTC Docket FTC–2020–0056 and are available at *www.regulations.gov.* For purposes of this Notice, all comments are referred to by their short docket number (*e.g.,* ''1''), rather than long docket number (*e.g.,* ''FTC–2020–0056–0001'').

[10] *See, e.g.,* Senators Sherrod Brown, Tammy Baldwin, Christopher Murphy, and Richard Blumenthal (''Senators'') (373); North American Insulation Manufacturers (631); *see also* Letter from Representative Frank Pallone, Jr., Chairman, and Representative Jan Schakowsky, Chair, Subcommittee on Consumer Protection and Commerce, U.S. House of Representatives (Oct. 15, 2020). *But see* Retail Industry Leaders Association (''RILA'') (570) (arguing low levels of enforcement activity suggest codifying the guidance into a rule is unnecessary).

[11] UIUC Accounting Group A13 (5); Delphine MUREKATETE, iMSA Program, University of Illinois at Urbana Champaign (21); Anonymous Anonymous (24); UIUC–BADM 403–A02 (25); Nirma Ramirez (26); Jaymee Westover (358); Joy Winzerling (419); United Steelworkers (526); Anonymous Anonymous (533); R–CALF USA (588).

[12] Chris Jay Hoofnagle (613) (advocating use of civil penalties to deter MUSA fraud).

[13] UIUC Accounting Group A13 (5); Chris Posey (7); Family Farm Action Alliance (543).

[14] See, *e.g.,* United Steelworkers (526); Alliance for American Manufacturing (''AAM'') (611).

[15] Honey Boynton (32); Holly Mastromatto (33); Doug Thompson (123); Lucilla Rinehimer (702).

[16] UIUC Accounting Group A13 (5); UIUC Group A06 Anonymous (22); Truth in Advertising, Inc. (''*TINA.org*'') (369); Senators (373); Southern Shrimp Alliance (380); Council for Responsible Nutrition (''CRN'') (569); Personal Care Products Council (''PCPC'') (587); Anonymous Anonymous (592); Alliance for AAM (611); National Association of Manufacturers (''NAM'') (623); Coalition for a Prosperous America (625).

[17] 15 U.S.C. 45a.

[18] UIUC Accounting Group A13 (50); UIUC Group A06 (22); *TINA.org* (369); Senators (373); Southern Shrimp Alliance (380); AAM (611); Coalition for a Prosperous America (625).

[19] *TINA.org* (369) (emphasis in original) (also arguing the Commission may draw support from the dictionary definition of ''labels,'' which includes digital labels).

[20] Id. at 2. *TINA.org* also suggested ''courts regularly interpret laws expansively in the face of technological innovation,'' and the ''possibility that Congress may not have anticipated the application of the term label to apply online does not change [the] outcome.''

would ''leave American consumers unprotected.'' [21] Accordingly, *TINA.org* concluded, ''[a]s a matter of statutory interpretation, the Commission *can* regulate digital MUSA labels. As a matter of consumer protection, the Commission *ought* to regulate digital MUSA labels.'' [22]

The Southern Shrimp Alliance (''SSA'') and AAM agreed, arguing Congress made an affirmative decision to defer to the FTC when it removed a definition of ''labels'' that appeared in initial drafts of the legislation.[23] Moreover, AAM argued the text of Section 45a specifically authorizes coverage of electronic labels because of the words ''the equivalent thereof'' in the phrase authorizing coverage of products introduced into commerce ''with a 'Made in the U.S.A.' or 'Made in America' label, or the equivalent thereof.'' [24] AAM argued the phrase refers to the ''equivalent'' of introducing a product into commerce with a label, *i.e.,* making a claim on a website.[25]

In contrast, four commenters asserted the proposed rule exceeds the scope of the Commission's rulemaking authority under Section 45a.[26] CRN and PCPC argued Section 45a's consistent use of the term ''label'' demonstrates Congress's intent to authorize a rule limited to labels on products, not one that would cover advertising generally.[27] An anonymous commenter argued Section 45a does not provide authority to regulate claims in mail order advertising materials as proposed in Section 323.3, so the proposed rule ''should be revised to only cover labels on products.'' [28] Should the FTC finalize a rule that purports to cover more than labels on products, NAM warned, the result could be ''lengthy litigation [, which would leave] manufacturers and consumers alike . . . without clear guidance at a time when manufacturers need as much regulatory certainty as possible.'' [29] Given these concerns over the scope of the Commission's rulemaking authority, Shirley Boyd stated the Commission should proceed pursuant to the Magnuson Moss Warranty-Federal Trade Commission Improvements Act to issue a broader rule covering MUSA advertising generally.[30]

2. Analysis

After reviewing the comments, the Commission has concluded proposed Section 323.3 falls within the scope of its authority under Section 45a. As described above, Section 45a authorizes the Commission to issue rules to govern labeling of products as ''Made in the U.S.A.'' or ''Made in America,'' or the equivalent thereof. Section 45a specifies: ''[t]o the extent any person introduces, delivers for introduction, sells, advertises, or offers for sale in commerce a product with a 'Made in the U.S.A.' or 'Made in America' label, or the equivalent thereof, in order to represent that such product was in whole or substantial part of domestic origin, such label shall be consistent with decisions and orders of the Federal Trade Commission.'' The Commission is empowered to ensure such labels are consistent with decisions and orders of the Federal Trade Commission defining unfair or deceptive acts or practices under Section 5. The Commission agrees with SSA and AAM that Congress's removal of a definition of ''label'' from Section 45a before its passage strongly suggests Congress deliberately chose to defer to the FTC's interpretation of the term in the context of MUSA claims.[31] Moreover, the Commission agrees with *TINA.org* that digital and physical labels are functionally equivalent, especially with the growth of e-commerce, and a failure to cover labels in print or electronic mail order catalogs or promotional materials would leave consumers without much-needed protection.[32]

The final rule does not cover MUSA claims in all advertising. Instead, as Section 323.3 explains, the rule covers *labels* appearing in all contexts, whether, for example, they appear on product packaging or online. With this clarification, the Commission adopts Section 323.3 as proposed.

B. ''All or Virtually All'' Standard

As described in Section I above, the NPRM proposed to codify the Commission's longstanding interpretation of Section 5's requirements governing substantiation of unqualified MUSA claims. This interpretation was first articulated in Commission cases dating back to the 1940s [33] and was formalized in the 1997 Policy Statement. Specifically, the NPRM proposed to prohibit unqualified MUSA claims on labels unless: (1) Final assembly or processing of the product occurs in the United States, (2) all significant processing that goes into the product occurs in the United States, and (3) all or virtually all ingredients or components of the product are made and sourced in the United States.

Although many commenters, particularly those with interest in food products, supported the decision to incorporate the ''all or virtually all'' guidance, others raised concerns. In particular, commenters questioned whether the ''all or virtually all'' standard represents current consumer understanding of MUSA claims. Some proposed alternative standards for consideration.

After analyzing these comments, as discussed below in Section II.B.3., the Commission has determined it has a reasonable basis to adopt the longstanding ''all or virtually all'' standard, and the rule provides appropriate and clear guidance to marketers.

1. Consumer Perception Testing

Six commenters argued the FTC should conduct new consumer perception testing before codifying the ''all or virtually all'' guidance into a rule.[34] They noted the Commission has not conducted comprehensive testing since the 1990s. CRN explained ''codifying a standard for unqualified U.S.-origin claims that is based on consumer perception data that has not been reanalyzed by the Commission in over 20 years'' is potentially problematic because ''[g]iven significant changes to the global economy, consumer perceptions of U.S.-origin claims are very likely to have changed over time and consumer perception in 1997, and even 2013, could be very different from how consumers perceive U.S.-origin claims today.'' [35] CTA agreed and asserted that proposing to codify the ''all or virtually standard'' without conducting new consumer perception

[21] *Id.* at 5.

[22] *Id.* at 3 (emphasis in original).

[23] Southern Shrimp Alliance (380); AAM (611).

[24] AAM (611). Coalition for a Prosperous America (625) agreed Section 45a's plain language permits coverage of electronic claims (arguing coverage is authorized where a ''substantial part'' of the product is of domestic origin) (citing Section 45a (''To the extent any person introduces, delivers for introduction, sells, advertises, or offers for sale in commerce a product with a 'Made in the U.S.A.' or 'Made in America' label, or the equivalent thereof, in order to represent that such product was in whole or substantial part of domestic origin, such label shall be consistent with decisions and orders of the Federal Trade Commission issued pursuant to section 45 of this title (emphasis added).'')).

[25] AAM (611).

[26] CRN (569); PCPC (587); Anonymous Anonymous (592); NAM (623).

[27] PCPC (587); CRN (569).

[28] Anonymous Anonymous (56).

[29] NAM (623) at 5.

[30] Shirley Boyd (6).

[31] Southern Shrimp Alliance (380); AAM (611).

[32] See *TINA.org* (369).

[33] See, *e.g.,* In re Vulcan Lamp Works, Inc., 32 F.T.C. 7 (1940).

[34] CRN (569); Consumer Technology Association (''CTA'') (579); Global Organization for EPA and DHA Omega-3s (604); American Association of Exporters and Importers (''AAEI'') (605); NAM (623); Pharmavite LLC (695).

[35] CRN (569).

testing ''put the cart before the horse.'' [36] NAM also encouraged the FTC to undertake a comprehensive review similar to the Commission's process in the 1990s before promulgating any rule.[37]

2. Alternative Standards

In addition to requesting the FTC conduct new perception testing, numerous commenters proposed alternatives to the ''all or virtually all'' standard. These proposals, which were based on policy arguments and were not accompanied by supporting consumer perception evidence, fell into two groups. On one hand, more than twenty commenters, mostly individual consumers, suggested unqualified MUSA claims should be limited to products 100% made in the United States. On the other hand, other commenters, mostly manufacturers, argued ''all or virtually all'' is too strict, and by incorporating it into a rule, the FTC could chill unqualified claims, discourage innovation, and harm industries where parts or ingredients are not available in the United States.[38] To address these concerns, this second group of commenters suggested alternatives: (1) Introducing a percentage-of-costs standard; (2) adopting a standard that makes allowances for imported parts or materials not available in the United States; (3) aligning with U.S. Customs and Border Protection's (''CBP'') substantial transformation standard; or (4) adding a safe harbor for ''good faith'' efforts to comply.

i. Percentage-Based Standards

Several commenters argued the Commission should provide marketers greater certainty by promulgating a ''bright line'' rule outlining a specific percentage of manufacturing costs that must be attributable to U.S. costs to substantiate an unqualified claim.[39] For example, NFI suggested the FTC could align the rule with California state law,[40] which permits manufacturers to make unqualified MUSA claims for products with up to 5% of the final wholesale value of the product attributable to articles, units, or parts of the merchandise obtained from outside the USA.[41]

RILA agreed a rule providing a bright-line percentage would help marketers comply, and suggested the FTC consider ''analogous federal regulations that incentivize U.S. manufacturing,'' and incorporate a 70% threshold for unqualified claims.[42] Alternatively, one commenter suggested a rule that would permit an unqualified claim for a product assembled in the United States where more than 50% of its value is based on components of U.S.-origin.[43]

Two representatives of the dietary supplement industry, the Global Organization for EPA and DHA Omega-3s (''GOED'') and Pharmavite LLC, made an alternative percentage-based proposal with different standards for active and inactive ingredients. Specifically, they argued consumers likely interpret an unqualified MUSA claim to mean 100% of a dietary supplement's active ingredients are made and sourced in the United States. They claimed, however, consumers care less about the origin of inactive ingredients. Accordingly, they contended the rule should incorporate a 10% tolerance for foreign-made or sourced inactive ingredients.[44]

ii. Unavailability Exemption

Other commenters argued the rule should allow marketers to make unqualified MUSA claims for products that include imported content only if the imported components are not available in the United States.[45] Some argued there should be a blanket exemption for such content. For example, Bradford White Corporation (''BWC'') suggested the rule broadly allow marketers to exclude foreign parts from the analysis if those parts cannot be ''reasonably sourced'' from a domestic manufacturer.[46] Others agreed the rule should permit unqualified claims for products that contain foreign content that cannot be sourced in the United States, but argued this exemption should be capped at a certain percentage of manufacturing costs. In NAM's view, a rule permitting marketers to incorporate an appropriate percentage of imported components or labor, not otherwise unavailable domestically, ''would give manufacturers clear and predictable rules and play a significant role in helping to encourage manufacturers to increase domestic investments in order to meet an attainable standard.'' [47]

iii. Substantial Transformation Analysis

Several commenters suggested the FTC adopt a ''substantial transformation'' standard for unqualified claims.[48] Three commenters from U.S. trade associations [49] explained harmonizing the FTC's rule with the CBP standard for determining foreign country of origin pursuant to the Tariff Act, 19 U.S.C. 1304, would provide clarity and alleviate the burden on U.S. companies that ''must navigate a number of different country of origin requirements.'' [50] AAFA explained adopting the ''substantial transformation'' standard would result in a ''clear, simple, and easy-to-understand rule.'' [51] The People's Republic of China (''China'') also argued, to avoid uncertainties and bias, the FTC should incorporate CBP's ''change in Tariff Classification'' analysis, as suggested in Article 9 of the World Trade Organization's (''WTO'') Agreement on Rules of Origin.[52]

iv. Good Faith Efforts To Comply

PCPC and RILA recommended the Commission provide safe harbors for two types of good-faith efforts to comply. PCPC, a trade association

[36] CTA (579).

[37] NAM (623).

[38] See, *e.g.,* CTA (579) (arguing the ''all or virtually all'' guidance deters innovation because many electronic product components are only made internationally); Personal Care Products Council (587) (guidance deters manufacturers from using maximum levels of U.S. parts and materials); AAEI (605) (guidance negatively impacts U.S. companies that will not risk making the claim).

[39] National Fisheries Institute (''NFI'') (628); RILA (570); TRAVIS HEDSTROM (600); Acuity Brands (609); NAM (623); American Coatings Association (''ACA'') (666) (stating marketers need guidance on percentage values or other guidance on how to deal with trace components of foreign/unknown origin).

[40] NFI (628).

[41] See Cal. Bus. & Prof. Code § 17533.7 (as revised in 2015).

[42] RILA (570).

[43] TRAVIS HEDSTROM (660).

[44] GOED (604); Pharmavite LLC (695).

[45] The California law makes such an allowance, although it is not unlimited. Specifically, California permits up to 10% (instead of 5%) of costs to be attributable to imported content if that content cannot be made or obtained in the USA for reasons other than cost. Cal. Bus. & Prof. Code § 17533.7.

[46] BWC (622). Indeed, BWC argued, given consumer expectations and current supply chains, rather than analyzing the percentage of costs attributable to U.S. versus foreign costs, it might be more appropriate to analyze the proportion of an entity's overall manufacturing workforce in the U.S. *Id.*

[47] NAM (623). See also Glenda Smith (612) (requesting more detail on how to handle raw materials not capable of being sourced in the USA).

[48] CBP defines ''substantial transformation'' as a manufacturing process that results in a new and different product with a new name, character, and use different from that which existed before. This standard does not take into account the origin of materials or parts. *See* 19 CFR part 134; *Energizer Battery, Inc.* v. *United States,* 190 F. Supp. 3d 1308 (Ct. Int'l Tr. 2016) (holding a substantial transformation occurs when a product emerges from a manufacturing process with a new name, character, and use, and the ''simple assembly'' of a limited number of components does not constitute a substantial transformation).

[49] International Precious Metals Institute, Inc. (''IPMI'') (520); AAEI (605); American Apparel and Footwear Association (''AAFA'') (675).

[50] AAEI (605). See also BWC (622) (raising concerns about increased regulatory burden).

[51] AAFA (675) (also suggesting the FTC ''eliminate'' qualified claims for any products that do not meet the ''substantial transformation'' threshold).

[52] China (699).

representing manufacturers, distributors, and suppliers of personal care products, suggested incorporating a safe harbor for ''good actors who are trying to overcome the difficulties in sourcing domestic components and materials.'' [53] PCPC explained, ''[a] safe harbor provision for unqualified claims would not dilute the purpose of the FTC's goal with this proposed rule—to deter bad actors from making false claims. Rather, such a provision would provide businesses who in good faith make every reasonable effort to make as much of their product as possible in the U.S. the flexibility to comply with any new regulations.'' [54]

Alternatively, RILA suggested that to avoid deterring retailers and marketplaces from offering products with MUSA labels the final rule should ''include an express statement . . . that allows retailers and marketplaces that have exercised reasonable due diligence to rely on documented supplier and vendor certifications to substantiate MUSA labeling claims.'' [55]

3. Analysis

The Commission has concluded it is not necessary to undertake additional consumer perception testing before adopting the proposed Rule. Accordingly, the Commission adopts the ''all or virtually all standard'' to govern unqualified claims as proposed in the NPRM. Although some commenters speculated consumer perception may have shifted over time, or argued the Commission should adopt a new standard for unqualified claims, there is no evidence on the record disputing the Commission's past findings that at least a significant minority of consumers expect a MUSA-advertised product to be ''all or virtually all'' made in the United States. Nor is there evidence suggesting new perception testing would find otherwise.

Indeed, the limited survey evidence submitted in conjunction with the 2019 workshop on MUSA claims suggested consumer perception has remained stable since the 1990s. Specifically, one panelist, Mark Hanna of Richline Group, Inc. submitted a survey, conducted in 2013, which found almost 3 in 5 Americans (57%) agree ''Made in America'' means all parts of a product, including any natural resources it contains, originated in the United States.[56] Additionally, the survey found 33 percent of consumers thought 100 percent of a product must originate in a country for that product to be labeled as ''Made'' in that country.[57] These findings are consistent with the FTC's 1995 survey, which found roughly 30 percent of consumers would be deceived by an unqualified MUSA claim for a product where 70 percent of the cost was incurred in the United States.[58] As Hanna explained during the workshop, ''at least 25% of the consumers were skeptical that if there's something introduced to that finished product other than something that originated in the US now, they didn't think it should be made in the USA.'' [59] Accordingly, the Commission has a reasonable basis to conclude the ''all or virtually all'' standard accurately represents current consumer perception regarding unqualified MUSA claims. Should future consumer research clearly establish the ''all or virtually all'' standard is inapplicable to a specific class of products, entities may petition the Commission for an exemption from the Rule's requirements, as discussed in Section III of this document.

While commenters proposed alternative standards that might promote certain policy goals, the Commission declines to adopt these alternative proposals for the reasons discussed below. Section 45a authorizes the Commission to issue rules to ensure products labeled as ''Made in the U.S.A.,'' or the equivalent thereof, comport with the requirements of Section 5 of the FTC Act that prohibit unfairness or deception. The ''all or virtually all'' standard is designed to prevent consumer deception and, therefore, the Commission declines to: (1) Adopt a bright-line, percentage-based standard; (2) include a broad carve-out for inputs not available in the United States; (3) incorporate CBP's ''substantial transformation'' standard; or (4) provide a safe harbor for good-faith efforts to comply.

First, percentage-based, bright-line rules could allow deceptive unqualified claims in circumstances where the low cost of the foreign input does not correlate to the importance of that input to consumers. For example, the Commission's enforcement experience has established unqualified U.S.-origin claims for watches that incorporate imported movements may mislead consumers because, although the cost of an imported movement is often low relative to the overall cost to manufacture a watch, consumers may place a premium on the origin and quality of a watch movement and consider the failure to disclose the foreign origin of this component to be material to their purchasing decision. Under those circumstances, the foreign movement likely is not a *de minimis* consideration for consumers, and an unqualified U.S.-origin claim for a watch containing an imported movement would likely deceive consumers.[60] The Policy Statement has instructed marketers since the 1990s that the cost of foreign versus U.S. parts and labor is only one factor to consider in determining how material a part may be to consumers.[61] Accordingly, the Commission declines to adopt a percentage-based standard because the ''all or virtually all'' standard is better tailored to prevent unqualified U.S.-origin claims that will mislead consumers in making purchasing decisions. By maintaining this precedent, the rule accounts for the likelihood consumers interpret MUSA claims somewhat differently for different product categories.

Second, the record similarly does not support excluding foreign content unavailable in the United States from the ''all or virtually all'' analysis. Specifically, as described above, consumer perception testing has consistently shown consumers expect products labeled as MUSA to contain no more than a *de minimis* amount of foreign content. There is no evidence this takeaway varies in scenarios where some parts or inputs are not available in the United States. Indeed, the Policy Statement explains unqualified claims for such products could be deceptive, for example, ''if the [nonindigenous] imported material constitutes the whole or essence of the finished product (*e.g.,* the rubber in a rubber ball or the coffee

[53] PCPC (587). Although not specifically advocating for a good-faith claim safe harbor, the Family Farm Action Alliance similarly argued the FTC should continue its practice of counseling inadvertent offenders into compliance (543).

[54] PCPC (587) at 3.

[55] RILA (570).

[56] Commission staff considered this study previously as part of a request for a staff advisory opinion on unqualified MUSA claims for recycled gold jewelry products. See Response to Request for FTC Staff Advisory Opinion (Sept. 9, 2014), *https://www.ftc.gov/system/files/documents/closing_letters/made-usa/140909madeisusajvc.pdf* (declining to provide an opinion stating MUSA claims for recycled jewelry do not deceive consumers based on perception evidence provided by Richline Group).

[57] See also Hanna, Transcript of *Made in USA: An FTC Workshop* (Sept. 26, 2019) (hereinafter, ''MUSA Tr.'') at 14 (study showed ''25% or 30% of [American consumers] really did feel that everything, including the natural resource, including the gold, had to be part of the final product in order to say it was made in the USA'').

[58] 62 FR 25020, 25036.

[59] Hanna, MUSA Tr. at 15.

[60] *See, e.g.,* FTC Staff Closing Letter to Niall Luxury Goods, LLC (Nov. 20, 2015), *available at https://www.ftc.gov/system/files/documents/closing_letters/nid/151120niall_letter.pdf.*

[61] *See* Policy Statement, 62 FR 63756, 63768.

beans in ground coffee).'' [62] However, the flexibility inherent in the ''all or virtually all'' analysis accounts for the possibility a marketer could substantiate an unqualified claim for a product containing nonindigenous raw materials if the manufacturer has evidence demonstrating the specific claim in context does not deceive consumers.[63]

Third, the record also does not support adopting government standards developed for other purposes (*e.g.,* the CBP substantial transformation standard developed for the imposition of tariffs) as part of the rule. Based on its enforcement experience, the Commission is concerned the standards adopted by CBP for purposes of calculating tariffs are not an appropriate fit for the Commission's regulation of MUSA claims on product labels for purposes of consumer disclosure. For example, there is ample evidence consumers care deeply about the source of the components used to manufacture drywall for construction projects. Under a substantial transformation analysis, drywall made wholly of materials from one nation, but substantially transformed in a different country, would be labeled as originating from the country where those materials were ultimately transformed into a final product. Marketers would not need to disclose the origin of the inputs other than labor (information highly material to many consumers). Thus, employing such a standard would in some cases conflict with the Rule's purpose of ensuring consumers have the material information necessary to make informed purchasing decisions.

Finally, the rule does not include an explicit carve-out for businesses that act in good faith. Courts have long held good faith is not a defense for a violation of Section 5 of the FTC Act,[64] and the Commission intends to enforce the rule consistent with this precedent. Violative claims made in good faith can still deceive and cause significant harm to consumers. However, the FTC clarifies it will continue to: (1) Advise marketers that, if provided in good faith, marketers can rely on information from suppliers about the domestic content in the parts, components, and other elements they produce; [65] (2) generally conserve enforcement resources for intentional, repeated, or egregious offenders; and (3) provide informal staff counseling where appropriate.

C. Requests for Additional Definitions and Other Clarifications

The Commission received several comments arguing the proposed Rule was unclear or provided insufficient guidance for marketers. To remedy these asserted problems, several commenters urged the FTC to add definitions for particular terms, including ''all or virtually all'' and ''significant processing.'' Other commenters expressed concern the Rule was not sufficiently clear about the range of claims it would cover, suggesting the FTC list additional synonyms for ''Made in USA'' to which the rule would apply. Finally, others requested a delayed effective date to allow marketers to update materials and come into compliance.

1. Definitions

More than twenty commenters recommended adding definitions or providing more information to clarify the rule. Without definitions, the commenters feared marketers would ''lack clear guidance for verifying MUSA claims'' and thus ''may be deterred from'' making them altogether.[66] Some of these commenters offered clarifying edits or proposed definitions, often as fallback positions to their main arguments advocating alternative standards entirely.[67]

In particular, in addition to commenters who recommended specifying percentage thresholds for ''all or virtually all,'' several commenters requested the Commission generally define the phrase, without providing specific information on what that definition should include (*e.g.,* factors considered, etc.).[68] As AAEI elaborated: ''One of the FTC's stated reasons for this proposed rulemaking is to 'provide more certainty to marketers about the standard for making unqualified claims on product labels.' Yet, the proposed 'all or virtually all' standard does not provide that certainty . . . It simply codifies the FTC's already existing ambiguous standards.'' [69] Two commenters specifically asked the Commission to incorporate information on whether marketers should consider the origin of product packaging into such a definition.[70]

Similarly, three commenters requested the Commission define ''significant processing.'' [71] As Pacific Coast Producers explained, the ''significant processing'' and ''all or virtually all'' ''terms have always been ambiguous, and the proposed rule does not help to remove the ambiguity or provide any meaningful guidance to industry.'' [72]

Finally, more than thirty commenters, primarily representing the domestic shrimp industry, argued the Commission should clarify that the definitions of ''mail order catalog'' and ''mail order promotional material'' include restaurant menus. As the Louisiana Shrimp Association (''LSA'') explained, ''inappropriate practices by some restaurants in offering menu items that falsely indicate to customers that imported shrimp is domestic, such as 'Gulf Shrimp'. . . not only confuse consumers, but fatally undermine the marketing efforts of restaurants that do carry domestic shrimp.'' [73] To solve this problem, SSA urged the Commission to ''exercise jurisdiction over 'Made in U.S.A.' statements on restaurant menus, as a form of 'Mail order promotional material' or 'mail order catalog.' '' [74]

2. Covered Claims

Several commenters suggested the Rule was not sufficiently clear about which U.S.-origin claims it covers. In particular, commenters requested a longer list of claims the Commission considers equivalent to ''Made in USA,'' as well as a specific statement that the Rule covers implied claims.

One commenter suggested adding ''constructed,'' ''fabricated,'' and ''assembled'' to the list.[75] Another

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[62] *Id.* at 63769 n.117.

[63] The Policy Statement explains in some cases ''where [a raw] material is not found or grown in the United States [and that raw material does not constitute the whole or essence of the finished product], consumers are likely to understand that a 'Made in USA' claim on a product that incorporates such materials (*e.g.,* vanilla ice cream that uses vanilla beans, which, the Commission understands, are not grown in the United States) means that all or virtually all of the product, except for those materials not available here, originated in the United States.'' *Id.* The Policy Statement provides that this guidance applies only to raw materials, not manufactured inputs.

[64] *See, e.g., FTC* v. *World Travel Vacation Brokers, Inc.,* 861 F.2d 1020, 1029 (7th Cir. 1988).

[65] *See* FTC, ''Complying with the Made in USA Standard,'' at 7–8 (Dec. 1998), *available at https://www.ftc.gov/system/files/documents/plain-language/bus03-complying-made-usa-standard.pdf* (also providing an example of a certification a marketer could request from a supplier that generally would constitute an acceptable basis for determining the appropriate country-of-origin designation for a product).

[66] RILA (570).

[67] *E.g.,* AAEI (605) (advocating adoption of the ''substantial transformation'' standard).

[68] See, *e.g.,* Shirley Boyd (6); Pacific Coast Producers (27); RILA (570); Vietnam (577); AAEI (605); NFI (628); ACA (666); AAFA (675).

[69] AAEI (605).

[70] Deontae Lafayette (20); Jaymee Westover (358).

[71] Shirley Boyd (6); Pacific Coast Producers (27); RILA (570).

[72] Pacific Coast Producers (27).

[73] LSA (404).

[74] SSA (380) (further explaining menus should fall under this definition because they are used in the direct sale or offer for sale of a product, are disseminated in print or can be delivered by electronic means, and are solely disseminated to solicit the purchase of a product).

[75] Frost Brown Todd LLC (522).

proposed ''processed,'' ''fabricated,'' and ''packaged.'' [76] Finally, one commenter suggested, to deter unscrupulous marketers effectively, the list should include claims that products are ''Distributed by:'' a company name followed by a U.S. address.[77]

Several commenters also asked the Commission to clarify that the Rule covers implied claims.[78] As AAM explained, ''the use of iconography, such as the American flag, used in the promotion of products should also be considered for its potential to evoke the positive qualities consumers associate with 'Made in USA,' as well as the prospect of such iconography being used in a deceptive manner.'' [79]

3. Effective Date

Finally, two commenters requested the FTC provide an extended compliance period before the rule's effective date. Specifically, ACA and McKenna Walsh argued companies would need time to come into compliance with the Rule. In their view, the FTC should delay implementation to give companies the opportunity to generate new marketing materials and run out old stock.[80]

4. Analysis

After analyzing the comments, the Commission finds the rule and its coverage clear on its face, with sufficient flexibility to address a changing marketplace. Therefore, as discussed further below, the Commission issues the rule without additional definitions or clarifications, or a delayed effective date.[81]

i. Definitions

The Commission declines to adopt definitions of ''all or virtually all'' and ''significant processing,'' or to expand the existing definition of ''mail order catalog'' or ''mail order promotional material.'' The Commission has issued extensive guidance to help marketers understand the ''all or virtually all'' standard. As the Policy Statement explains, ''A product that is all or virtually all made in the United States will ordinarily be one in which all significant parts and processing that go into the product are of U.S. origin.'' In other words, where a product is labeled or otherwise advertised with an unqualified claim, it should contain only a *de minimis,* or negligible, amount of foreign content. Although there is no single ''bright line'' to establish when a product is or is not ''all or virtually all'' made in the United States, there are a number of factors to consider in making this determination. First, in order for a product to be considered ''all or virtually all'' made in the United States, the final assembly or processing of the product must take place in the United States. Beyond this minimum threshold, the Commission will consider other factors, including but not limited to the portion of the product's total manufacturing costs attributable to U.S. parts and processing; how far removed from the finished product any foreign content is; and the importance of the foreign content to the form or function of the product. Accordingly, the Commission's existing guidance and enforcement documents, including the Policy Statement, decisions and orders enforcing the ''all or virtually all'' standard, and staff closing letters, together provide ample guidance to marketers.

As discussed above in Section II.B.3., ''all or virtually all'' and ''significant processing'' intentionally incorporate flexibility to allow marketers to substantiate their claims consistent with consumer perception of their particular products. The Commission's enforcement program has long recognized the need for such flexibility as described in the Policy Statement, which was based on the Commission's decisions and orders. The Commission has continued to follow this flexible approach, and incorporated it into its post-Policy Statement decisions and orders. Adding specific definitions for these terms may increase clarity for marketers in the short term because the rule covers so many product categories across a range of circumstances, but the Commission has determined adding further specificity also increases the risk the rule would chill certain non-deceptive claims. Marketers seeking additional guidance may look to the Policy Statement, decisions and orders, and other Commission guidance to understand how the FTC has analyzed ''all or virtually all'' and ''significant processing.'' [82]

The Commission also declines to adopt a definition of ''mail order catalog'' or ''mail order promotional material'' that specifically incorporates restaurant menus. The Commission has not reviewed perception evidence regarding consumer understanding of MUSA claims on restaurant menus, and therefore declines to define such claims as covered ''labels'' for purposes of Section 45a.

ii. Covered Claims

The Commission also concludes it is unnecessary to revise the definitions to provide an expanded list of synonyms for the term ''Made in U.S.A.,'' or provide further clarification the rule covers implied claims. Section 323.1 as proposed already defines ''Made in U.S.A.'' as ''*any unqualified representation, express or implied,* that a product or service, or a specified component thereof, is of U.S. origin, including, but not limited to, a representation that such product or service is 'made,' 'manufactured,' 'built,' 'produced,' 'created,' or 'crafted' in the United States or in America, *or any other unqualified U.S.-origin claim*'' (emphasis added).[83]

The list of equivalents to ''Made in USA'' set forth in Section 323.1 is not exhaustive because the means of communicating U.S. origin are too numerous to list. The Commission believes the non-exhaustive list of examples given provide sufficient guidance on the scope of covered express and implied claims. These examples are based on the Commission's decades of enforcement experience addressing MUSA claims. For other claims, the Commission will analyze them in context, including the terms used, their prominence, and their proximity to images and other text.

iii. Effective Date

Lastly, the Commission declines to delay the rule's effective date. As discussed above in Section I, the rule codifies the FTC's longstanding guidance on MUSA claims. The FTC has incorporated the ''all or virtually all'' standard into decisions and orders and guidance for industry and the public since the 1990s.[84] Because the rule merely codifies these longstanding enforcement principles and imposes no new requirements on marketers, the Commission concludes a delayed effective date is unnecessary.

[76] R–CALF USA (588).

[77] Salvatore J. Versaggi (496).

[78] See, *e.g.,* Shirley Boyd (6); Power Planter Inc. (325); AAM (611); American Shrimp Processors Association (''ASPA'') (633).

[79] AAM (611).

[80] ACA (666); McKenna Walsh (581).

[81] As discussed in Section III, the Final Rule contains a provision clarifying that, in appropriate circumstances, covered entities may petition the Commission for an exemption from the Rule's requirements.

[82] See Policy Statement, 62 FR 63756, 63768 (Dec. 2, 1997).

[83] 16 CFR 323.1.

[84] *See generally https://www.ftc.gov/tips-advice/business-center/advertising-and-marketing/made-in-usa.* The Commission has explained that prior to the 1990s, this standard was described as the ''wholly domestic'' standard, and both ''wholly domestic'' and ''all or virtually all'' refer to the concept that ''unqualified claims of domestic origin have been treated as claims that the product was in all but *de minimis* amounts made in the United States.'' 62 FR 63756 (Dec. 2, 1997).

D. Guidance for Specific Industries

Some commenters requested tailored guidance for specific industries. Specifically, representatives of the beef and shrimp industries requested guidance on whether the Rule would apply to their products, and specific guidance on how to apply ''all or virtually all'' in these contexts.

1. Beef

The Commission received more than 450 comments urging the Commission to clarify that the rule applies to beef products. These stakeholders, primarily U.S. ranchers and industry groups representing domestic ranchers, generally supported the rule and argued it should supersede United States Department of Agriculture (''USDA'') guidance on using ''Product of USA'' claims on beef product labels. Although they acknowledged the USDA's longstanding authority over beef labeling, they expressed concern USDA's Food Safety Inspection Service (''FSIS'') Food Standards and Labeling Policy Book currently authorizes producers to place ''Product of USA'' labels on beef products processed in the USA but comprised of cattle born, raised, and slaughtered overseas. These commenters argued such labels deceive consumers, and ''put U.S. family farmers and ranchers at an unfair disadvantage in the marketplace, because they are not able to differentiate their domestically produced meat and meat products from foreign produced meat and meat products.'' [85] Accordingly, they argued the ''all or virtually all'' standard should apply to beef products, and beef products should only bear a ''Product of USA'' label if they derive from animals born, raised, slaughtered, and processed in the United States.[86]

In contrast, five commenters argued Congress granted the USDA generally, and the FSIS specifically, authority to address country-of-origin labeling for meat and meat food products. Therefore, they argued, the FTC should defer to the USDA on this issue.[87] The North American Meat Institute and the Meat Importers' Council of America submitted a joint comment stating beef commenters' concerns ''are misplaced because they fail to recognize that the [USDA's FSIS] has primary jurisdiction over the meat and poultry labeling through the authority provided in the Federal Meat Inspection Act (FMIA) and the Poultry Products Inspection Act (PPIA).'' [88] The Montana Stockgrowers Association agreed, explaining that even though it ''supports USA beef as being defined as born, raised, harvested, and processed in the USA . . . [its members] think the [USDA] should be the lead agency to address enforcement of labels that include all meat products.'' [89] Moreover, some commenters raised concerns applying the FTC's rule to beef products could lead to challenges in, or even sanctions by, the WTO, given past proceedings relating to beef labeling.[90]

2. Shrimp

The Commission also received dozens of comments from representatives of the domestic shrimp industry. Most of these expressed general support for the proposed rule, and recommended the FTC allow MUSA labels only for shrimp caught, harvested, and processed in the United States.

Although they expressed enthusiasm for the potential application of the proposed MUSA rule's ''all or virtually all'' standard in shrimp labeling, commenters acknowledged that USDA's Country of Origin Labeling (''COOL'') regulations [91] have primary authority in this space. The COOL regulations require ''retail establishments'' to provide country-of-origin information for wild and farm-raised fish and shellfish,[92] and incorporate specific standards under which marketers can label shrimp as MUSA.[93] However, commenters identified a possible gap in regulatory coverage, explaining that, pursuant to USDA Agricultural Marketing Service (''AMS'') regulations governing country-of-origin labeling for fish and shellfish, COOL does not apply to processed shrimp products, including breaded or marinated shrimp.[94] In addition, as described above in Section II.C.1., these commenters noted that USDA COOL regulations do not apply to claims regarding shrimp or shrimp products on restaurant menus.[95] Thus, these commenters urged the FTC to ''us[e] its authority to enforce the MUSA rule [with respect to these categories of shrimp products, thereby] . . . filling a void in federal labeling accountability and providing certainty to the seafood market during this time of widespread economic instability.'' [96]

3. Analysis

The FTC shares jurisdiction over country-of-origin claims for agricultural products with the USDA and, in some instances, the Food and Drug Administration (''FDA''). USDA and FDA have primary jurisdiction over labeling issues for the food products within their purview.[97] Section 45a specifically provides that ''Nothing in this section shall preclude the application of other provisions of law relating to labeling.'' [98] Accordingly, Section 323.5(a) of this rule makes clear that the rule does not supersede, alter, or affect the application of any other federal statute or regulation relating to country-of-origin labeling requirements, including but not limited to regulations issued under the FMIA, 21 U.S.C. 601 *et seq.;* the Poultry Products Inspection Act, 21 U.S.C. 451 *et seq.;* or the Egg Products Inspection Act, 21 U.S.C. 1031 *et seq.*

Congress has granted the USDA's FSIS specific authority to regulate agricultural products, including, among others, beef and chicken products. The USDA regulates labels on meat products sold at retail pursuant to the FMIA, which prohibits misleading labels.[99] Although FSIS's Policy Book has permitted voluntary claims of ''Product of USA'' for imported products under FSIS's jurisdiction, including beef products, processed in the USA, FSIS recently explained this guidance ''may be misleading to consumers and may not meet consumer expectations of what 'Product of USA' signifies.'' [100] Accordingly, the USDA announced plans to initiate a rulemaking to alleviate any potential confusion in the

[85] North Dakota Farmers Union (412).

[86] The Commission also received more than 150 comments stating country-of-origin labeling should be mandatory for beef products.

[87] See, *e.g.,* Mexico's National Confederation of Livestock Organizations (431); North American Meat Institute and Meat Importers' Council of America (508); National Cattlemen's Beef Association (589); Montana Stockgrowers Association (635); Embassy of Canada (637). Some of these stakeholders argued the FTC should specifically exempt meat labeling from the Rule's coverage.

[88] North American Meat Institute and the Meat Importers' Council of America (508). *See also* National Cattlemen's Beef Association (589) (''remind[ing] FTC that the Federal Meat Inspection Act of 1906 (21 U.S.C. 601 *et seq.*) grants the U.S. Department of Agriculture (USDA) primary jurisdiction over all meat food product oversight activities, including the approval and verification of geographic and origin labeling claims.'').

[89] Montana Stockgrowers Association (635).

[90] Mexico's National Confederation of Livestock Organizations (431); National Cattlemen's Beef Association (589); see also Embassy of Canada (637) (stating, in light of 2015 WTO proceedings, the Government of Canada ''will continue to closely monitor the development of the proposed'' Rule).

[91] 7 CFR part 60.

[92] 7 U.S.C. 1638(1).

[93] 7 CFR 60.128.

[94] ASPA (633) (citing 7 CFR 60.119).

[95] See, *e.g.,* Southern Shrimp Alliance (380).

[96] ASPA (633), at 2.

[97] See Memorandum of Understanding between Federal Trade Commission and the Food and Drug Administration, 36 FR 18539 (Sept. 16, 1971).

[98] 15 U.S.C. 45a.

[99] 21 U.S.C. 601(n)(1); 9 CFR 317.8(a) (prohibiting labels that convey ''any false indication of origin'').

[100] *See* R. Edelstein Letter to E. Drake (Mar. 26, 2020).

marketplace.[101] As that proceeding unfolds, the Commission remains committed to engaging with the USDA to ensure American consumers receive truthful and accurate information about the beef products they buy.

Under its COOL regulations, USDA's AMS has primary authority over country-of-origin labels for most fish and shellfish products.[102] Because Section 45a's general grant of rulemaking authority does not authorize the Commission to issue regulations that would preclude the application of existing statutes and regulations addressing agricultural product labeling, the FTC defers to AMS's regulatory scheme for COOL for fish and shellfish. Section 323.5 makes clear the rule does not supersede, alter, or affect any other federal statute or regulation relating to country-of-origin labeling requirements. However, to the extent certain, limited categories of agricultural products fall outside USDA's jurisdiction, the Commission will analyze claims on a case-by-case basis and consult with other agencies as appropriate.[103]

E. Other Proposals

Some commenters proposed a series of other amendments, arguing variously that the Rule should preempt state law entirely; [104] cover MUSA advertising generally; [105] make country-of-origin labeling mandatory for all products; [106] incorporate provisions relating to qualified U.S.-origin claims; [107] and include language specifically correlating penalties to firm sizes.[108] The Commission declines to adopt these changes, which are inconsistent with its rulemaking mandate under Section 45a. As discussed above, Section 45a grants the Commission authority to issue rules to prevent unfair or deceptive acts or practices relating to MUSA labeling. Specifically, Section 45a authorizes the Commission to issue rules to require MUSA labeling to ''be consistent with decisions and orders of the Federal Trade Commission issued pursuant to [Section 5 of the FTC Act].'' The FTC may seek civil penalties for violations of such rules.

1. Preemption

The Commission intends to preempt state statutes or regulations that are inconsistent with the Commission's rules only to the extent of the inconsistency.[109] When it enacted Section 45a, Congress declined to expressly preempt state regulation or otherwise demonstrate a clear intent for federal law to occupy the field of regulation in question.[110] Accordingly, Section 323.5 of the Rule preempts a state statute, regulation, order, or interpretation ''to the extent that such statute, regulation, order, or interpretation is inconsistent with the provisions of this part, and then only to the extent of the inconsistency.'' Moreover, the rule makes clear that a state statute, regulation, order, or interpretation is not inconsistent with the rule if the protection such statute, regulation, order, or interpretation affords any consumer is greater than the protection provided by the rule.

2. MUSA Advertising Generally

Some commenters encouraged the Commission to expand the proposed rule to cover all advertising that includes any U.S.-origin claim, rather than focusing as proposed on MUSA labeling.[111] Section 45a, however, is directed at labels on products declaring that a product is ''in whole or substantial part of domestic origin'' and thus may be labeled ''Made in the U.S.A.,'' or the equivalent thereof. The statute does not explicitly address general advertising claims beyond the context of labeling. Accordingly, in enacting this rule, the Commission has not focused on advertising more generally, but retains the proposed rule's focus on MUSA claims on labels or in mail order or catalog advertising, including in online marketplaces, that depict a product label. However, the FTC's general authority under Sections 5 and 12 of the FTC Act covers advertising, including advertising of qualified and unqualified MUSA claims.[112]

3. Mandatory Country-of-Origin Labeling

Other commenters recommended the Commission make country-of-origin labeling mandatory. For example, the Made in USA Foundation proposed that the Rule should require that all advertisements for specified categories of products, including all products advertised for sale on the internet, disclose the country of origin of the products in a clear and prominent manner.[113] While the Commission acknowledges that many consumers may find such information to be valuable in many circumstances, Section 45a does not authorize the Commission to establish a mandatory country-of-origin labeling scheme. The statute grants the Commission authority to issue rules to ensure that Made in USA claims are not deceptive and are consistent with the Commission's decisions and orders defining unfair or deceptive acts or practices under Section 5. Accordingly, the Commission lacks authority under Section 45a to enact this proposal.

4. Qualified U.S.-Origin Claims

Some commenters also argued that the rule should also address qualified U.S.-origin claims. The United Steelworkers asserted that, ''[a]s firms with global supply chains seek to benefit from the value consumers place in products with American content, we must ensure that qualified claims accurately represent the level of value creation in the United States.'' [114] Section 45a, however, is directed to labels on products declaring that a product is ''in whole or substantial part of domestic origin,'' and therefore the Rule is directed to unqualified claims, rather than more varied qualified claims. Accordingly, the FTC will continue to address deceptive qualified U.S.-origin claims under its general

[101] *Id.*

[102] 7 U.S.C. 1638(1); 7 CFR 60.128.

[103] The FTC notes deceptive claims on restaurant menus appear to be largely a regional issue, and therefore are being addressed through state legislation. *See, e.g.,* La. R.S. § 40:5.5.4 (requiring food service establishments to provide notice to consumers if crawfish or shrimp is imported); La. R.S. § 56:578.14 (''No owner or manager of a restaurant that sells imported crawfish or shrimp shall misrepresent to the public, either verbally, on a menu, or on signs displayed on the premises, that the crawfish or shrimp is domestic.''). FTC staff will continue to monitor this issue.

[104] BWC (622); AAFA (675). Additionally, PCPC (589) argued the Rule should specifically preempt a private right of action. However, two commenters agreed with the section as drafted as a means to ''ensure regulatory certainty and consistency of product U.S. origin labels nationwide.'' RILA (570). See also NAM (623) (recognizing the ''value of utilizing preemption to create a uniform MUSA standard'').

[105] UIUC Accounting Group A13 (5); Shirley Boyd (6); UIUC—BADM 40—A02 (22); Senators (373); United Steelworkers (526); Women Involved in Farm Economics/Pam Potthoff Beef Chairman (672).

[106] The Commission received 30 comments arguing country-of-origin labeling should be mandatory for all products. See, *e.g.,* J R. Brookshire (9). Additionally, six commenters argued specifically in favor of mandatory country-of-origin labeling for all products sold online. See, *e.g.,* Made in USA Foundation (2).

[107] Twelve commenters requested coverage of qualified claims. See, *e.g.,* Shirley Boyd (6); United Steelworkers (526); AAM (611); CPA (625).

[108] Six commenters argued civil penalties should be linked to company size. *See, e.g.,* Chris Posey (7).

[109] *See City of New York* v. *FCC,* 486 U.S. 57, 64 (1988) (''The statutorily authorized regulations of an agency will pre-empt any state or local law that conflicts with such regulations or frustrates the purposes thereof.'').

[110] *See, e.g., Mozilla* v. *FCC,* 940 F.3d 1, 74–75 (D.C. Cir. 2019).

[111] *See, e.g.,* Shirley Boyd (6) (''The FTC's final rules should apply to labeling, advertising and other promotional and marketing materials in addition to labels and mail order catalogs/promotional materials.'').

[112] 15 U.S.C. 45(a), 52.

[113] Made in USA Foundation (2).

[114] United Steelworkers (526).

authority in Section 5 of the FTC Act.[115] Marketers should continue to consult the Policy Statement for guidance on the application of the Commission's Section 5 analysis to such claims including, but not limited to, ''Assembled in USA,'' claims indicating the amount of U.S. content (*e.g.,* ''60% U.S. Content''), claims indicating the parts or materials that are imported (*e.g.,* ''Made in USA from imported leather''), or claims about specific processes or parts (*e.g.,* claims a product is ''designed,'' ''painted,'' or ''written'' in the United States).

5. Civil Penalties

Some commenters argued that larger businesses may not be sufficiently deterred by the current maximum civil penalty amounts for violations of Commission rules and recommended that civil penalties should be increased for larger firms.[116] The Commission lacks authority, however, to establish civil penalty maximums that depart from the levels provided by statute. Civil penalty amounts for violations of the Commission's rules are established by the FTC Act.[117] Nonetheless, the Commission believes that its civil penalty authority generally provides an effective deterrent against rule violations, and notes that civil penalties for violations of a rule are assessed per violation. Moreover, the FTC Act establishes a series of factors for courts to consider in assessing appropriate civil penalty amounts in individual enforcement matters, including ''the degree of culpability, any history of prior such conduct, ability to pay, effect on ability to continue to do business, and such other matters as justice may require.'' [118] To the extent firm size is an appropriate consideration within one or more of these factors, the Commission will take that factor into account in seeking civil penalties.

III. Final Rule

For the reasons described above, the Commission has determined to adopt the substantive provisions of the rule as initially proposed. Specifically, the rule covers labels on products that make unqualified MUSA claims. It codifies the Commission's previous MUSA Decisions and Orders and prohibits marketers from making unqualified MUSA claims on labels unless: (1) Final assembly or processing of the product occurs in the United States, (2) all significant processing that goes into the product occurs in the United States, and (3) all or virtually all ingredients or components of the product are made and sourced in the United States. The rule also covers labels making unqualified MUSA claims appearing in mail order catalogs or mail order advertising.

To avoid confusion or perceived conflict with other country-of-origin labeling laws and regulations, the rule specifies that it does not supersede, alter, or affect any other federal or state statute or regulation relating to country-of-origin labels, except to the extent that a state country-of-origin statute, regulation, order, or interpretation is inconsistent with the rule.

Finally, the Commission has adopted a new Section, 323.6, to address commenter concerns about the applicability of the ''all or virtually all'' standard across product categories. This provision allows marketers and other covered persons to seek full or partial exemptions if they can demonstrate application of the rule's requirements to a particular product or class of product is not necessary to prevent the acts or practices to which the rule relates. The Commission's rules of practice governing petitions for rulemaking provide the procedures for submitting such petitions.[119] Pursuant to this process, interested persons may file relevant consumer perception evidence and data with the Commission. If the Commission deems the petition sufficient to warrant further consideration, it will follow the procedures outlined in Section 1.25 of its rules.

IV. Paperwork Reduction Act

The Paperwork Reduction Act (''PRA''), 44 U.S.C. 3501 *et seq.,* requires federal agencies to seek and obtain Office of Management and Budget (''OMB'') approval before undertaking a collection of information directed to ten or more persons. The Commission has determined that there are no new requirements for information collection associated with this final rule.

V. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA''), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996, requires that the Commission provide an Initial Regulatory Flexibility Analysis with a proposed rule, and a Final Regulatory Flexibility Analysis with the final Rule, unless the Commission certifies that the proposed Rule will not have a significant impact on a substantial number of small entities.[120]

The Commission recognizes some affected entities may qualify as small businesses under the relevant thresholds. However, the Commission anticipates that the final Rule will not have the threshold impact on small entities. First, the rule includes no new barriers to making claims, such as reporting or approval requirements. Second, the rule merely codifies standards established in FTC enforcement Decisions and Orders for decades. Therefore, the Rule imposes no new burdens on law-abiding businesses.

Accordingly, the Commission certifies that the final rule will not have a significant economic impact on a substantial number of small businesses. Although the Commission certifies under the RFA that the amendment will not have a significant impact on a substantial number of small entities, the Commission has determined, nonetheless, that it is appropriate to publish a Final Regulatory Flexibility Analysis in order to explain the impact of the amendments on small entities as follows:

A. Description of the Need for and Objectives of the Rule

The Commission proposed the MUSA Labeling Rule for two primary reasons: To strengthen its enforcement program and make it easier for businesses to understand and comply with the law. Specifically, by codifying the existing standards applicable to MUSA claims in a rule as authorized by Congress, the FTC will be able to provide more certainty to marketers about the standard for making unqualified claims on product labels, without imposing any new obligations on market participants. In addition, enactment of the Rule will enhance deterrence by authorizing civil penalties against those making unlawful MUSA claims on product labels.

B. Issues Raised by Comments in Response to the IRFA

The Commission received six comments specifically related to the impact of the Rule on small businesses.[121] Of those six, all

[115] 15 U.S.C. 45(a).

[116] Chris Posey (7).

[117] *See* 15 U.S.C. 45(m)(1)(A) (establishing civil penalties for violations of Commission rules); *see also* 16 CFR 1.98 (stating currently applicable maximum civil penalty amounts).

[118] 15 U.S.C. 45(m)(1)(C).

[119] *See* 16 CFR 1.25.

[120] 5 U.S.C. 603–605.

[121] Anonymous (24) (commenter is unaware of small entities affected by the NPRM); UIUC—BADM 403—A02 (25) (commenter is unaware of small entities affected by the NPRM); Family Farm Action Alliance (543) (anticipating positive economic outcomes for small business entities as a result of the rule); Leo McDonnell (578) (anticipating benefits for small businesses, including ranchers and feeders); McKenna Walsh (581) (stating the Rule will be helpful for small businesses lacking resources to engage in MUSA litigation); Natural

Continued

anticipated the rule would benefit small businesses, with the exception of the Natural Products Association, which argued that the Rule would impose costs on dietary supplement manufacturers that would have to relabel products.[122] The FTC notes that the rule imposes no new requirements on dietary supplement manufacturers, and that products requiring relabeling as a result of the FTC's rule were likely deceptively labeled prior to the Rule's publication. The Chief Counsel for Advocacy of the Small Business Administration did not submit comments.

C. Estimate of Number of Small Entities to Which the Rule Will Apply

The Small Business Administration estimates that in 2018 there were 30.2 million small businesses in the United States. The rule will apply to small businesses that make MUSA claims on product labels. The Commission estimates the rule will not have a significant impact on these small businesses because it does not impose any new obligations on law-abiding businesses; rather, it merely codifies standards established in FTC enforcement Decisions and Orders for decades.

D. Projected Reporting, Recordkeeping, and Other Compliance Requirements, Including Classes of Covered Small Entities and Professional Skills Needed To Comply

The rule imposes no affirmative reporting or recordkeeping requirements. The rule's compliance requirements, consistent with the Policy Statement and longstanding Commission case law, require that marketers may not make unqualified U.S.-origin claims on product labels unless final assembly or processing of the product occurs in the United States, all significant processing that goes into the product occurs in the United States, and all or virtually all ingredients or components of the product are made and sourced in the United States. The small entities potentially covered by the rule will include all such entities that make MUSA claims on product labels. The rule codifies the standard for MUSA claims established in Commission Decisions and Orders, and no new obligations are anticipated.

E. Description of Steps Taken To Minimize Significant Economic Impact, if Any, on Small Entities, Including Alternatives

The Commission sought comment and information on the need, if any, for alternative compliance methods that would reduce the economic impact of the rule on such small entities. Several commenters proposed alternatives to the proposed rule including: (1) Introducing a percentage-of-costs standard; (2) adopting a standard that makes allowances for imported parts or materials not available in the United States; (3) aligning with CBP's substantial transformation standard; or (4) adding a safe harbor for ''good faith'' efforts to comply. Other commenters proposed that the Commission provide for a delayed effective date to allow businesses additional time to comply. As discussed above, the Commission has declined to adopt these alternatives because it believes they would undermine the effectiveness of the rule. In addition, the Natural Products Association recommended the FTC incorporate an example specific to dietary supplements.[123] The Commission has declined to include examples specific to any particular industry in the Rule. The rule codifies the standards articulated in Commission enforcement decisions that have been applicable to MUSA claims for decades. FTC guidance and enforcement decisions provide numerous examples demonstrating how to apply the ''all or virtually all'' standard in a variety of industries. Accordingly, the Commission has concluded that it is unnecessary to provide industry-specific examples in the Rule.

As described previously, the rule merely codifies standards already established in FTC enforcement Decisions and Orders. It does not impose new substantive obligations on businesses that have already been complying with their obligations to avoid deceptive claims under Section 5 of the FTC Act. Under these circumstances, the Commission does not believe a special exemption for small entities or significant compliance alternatives are necessary or appropriate to minimize the compliance burden, if any, on small entities while achieving the intended purposes of the rule. Nonetheless, the Commission has adopted a provision allowing covered persons to petition the Commission for an exemption from the Rule if application of the rule's requirements is not necessary to prevent the acts or practices to which the rule relates.

VI. Other Matters

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), the Office of Information and Regulatory Affairs has designated this rule as not a ''major rule,'' as defined by 5 U.S.C. 804(2).

VII. Final Rule Language

List of Subjects in 16 CFR Part 323

Labeling, U.S. origin.

■ For the reasons stated in the preamble, the Federal Trade Commission adds part 323 to subchapter C of title 16 of the Code of Federal Regulations as follows:

PART 323—MADE IN USA LABELING

Sec.
323.1 Definitions.
323.2 Prohibited acts.
323.3 Applicability to mail order advertising.
323.4 Enforcement.
323.5 Relation to Federal and State laws.
323.6 Exemptions.

Authority: 15 U.S.C. 45a.

§ 323.1 Definitions.

As used in this part:

(a) The term *Made in the United States* means any unqualified representation, express or implied, that a product or service, or a specified component thereof, is of U.S. origin, including, but not limited to, a representation that such product or service is ''made,'' ''manufactured,'' ''built,'' ''produced,'' ''created,'' or ''crafted'' in the United States or in America, or any other unqualified U.S.-origin claim.

(b) The terms *mail order catalog* and *mail order promotional material* mean any materials, used in the direct sale or direct offering for sale of any product or service, that are disseminated in print or by electronic means, and that solicit the purchase of such product or service by mail, telephone, electronic mail, or some other method without examining the actual product purchased.

§ 323.2 Prohibited acts.

In connection with promoting or offering for sale any good or service, in or affecting commerce as ''commerce'' is defined in section 4 of the Federal Trade Commission Act, 15 U.S.C. 44, it is an unfair or deceptive act or practice within the meaning of section 5(a)(1) of the Federal Trade Commission Act, 15 U.S.C. 45(a)(1), to label any product as Made in the United States unless the final assembly or processing of the product occurs in the United States, all significant processing that goes into the product occurs in the United States, and

Products Association (618) (stating the rule would require small dietary supplement businesses to relabel products).

[122] Natural Products Association (618).

[123] *Id.*

all or virtually all ingredients or components of the product are made and sourced in the United States.

§ 323.3 Applicability to mail order advertising.

To the extent that any mail order catalog or mail order promotional material includes a seal, mark, tag, or stamp labeling a product Made in the United States, such label must comply with § 323.2.

§ 323.4 Enforcement.

Any violation of this part shall be treated as a violation of a rule under section 18 of the Federal Trade Commission Act, 15 U.S.C. 57a, regarding unfair or deceptive acts or practices.

§ 323.5 Relation to Federal and State laws.

(a) *In general.* This part shall not be construed as superseding, altering, or affecting the application of any other federal law or regulation relating to country-of-origin labeling requirements, including but not limited to the Federal Meat Inspection Act, 21 U.S.C. 601 *et seq.,* the Poultry Products Inspection Act, 21 U.S.C. 451 *et seq.,* and the Egg Products Inspection Act, 21 U.S.C. 1031 *et seq.* In addition, this part shall not be construed as superseding, altering, or affecting any other State statute, regulation, order, or interpretation relating to country-of-origin labeling requirements, except to the extent that such statute, regulation, order, or interpretation is inconsistent with the provisions of this part, and then only to the extent of the inconsistency.

(b) *Greater protection under State law.* For purposes of this section, a State statute, regulation, order, or interpretation is not inconsistent with the provisions of this part if the protection such statute, regulation, order, or interpretation affords any consumer is greater than the protection provided under this part, as determined by the Commission on its own motion or upon the petition of any interested party.

§ 323.6 Exemptions.

Any person to whom this Rule applies may petition the Commission for a partial or full exemption. The Commission may, in response to petitions or on its own authority, issue partial or full exemptions from this part if the Commission finds application of the Rule's requirements is not necessary to prevent the acts or practices to which the Rule relates. The Commission shall resolve petitions using the procedures provided in § 1.25 of this chapter. If appropriate, the Commission may condition such exemptions on compliance with alternative standards or requirements to be prescribed by the Commission.

By direction of the Commission.

April J. Tabor,

Secretary.

The following Appendices will not Appear in the Code of Federal Regulations.

Appendix I: Statement of Commissioner Rohit Chopra Joined by Chair Lina Khan and Commissioner Rebecca Kelly Slaughter

Today, the Commission has voted to adopt a final Made in USA rule. The final rule reflects a substantial number of comments from the public, which overwhelmingly supported this policy change by the Commission. By formally codifying this rule, the Commission has activated a broader range of remedies, including the ability to seek redress, damages, penalties, and other relief from those who lie about a Made in USA label. The rule will especially benefit small businesses that rely on the Made in USA label, but lack the resources to defend themselves from imitators.

Absent this rule, the Commission would be unable to seek this full set of sanctions. Importantly, this is a ''restatement rule,'' which affirms longstanding guidance and legal precedent with respect to Made in USA labels—thereby imposing no new obligations on manufacturers and sellers. Because of the stricter sanctions they trigger, restatement rules such as this one will increase fraud deterrence and ensure that victims can be made whole.

Background on the FTC's Permissive Policy on Made in USA Fraud

For decades, there has been a bipartisan consensus among Commissioners that Made in USA fraud should not be penalized. In my view, this policy posture was in direct contravention of both the letter and spirit of the law Congress enacted.

In 1994, shortly after the North American Free Trade Agreement took effect, Congress enacted legislation to protect the integrity of our national brand by explicitly authorizing the FTC to trigger penalties and other relief for Made in USA fraud, but only after formally codifying a rule.[1] However, the Commission never even proposed one.[2]

Instead, over the past quarter century, Commissioners implemented a highly permissive Made in USA fraud policy, where violators faced essentially no consequences whatsoever. Even in cases of blatant abuse of the Made in USA label, Commissioners routinely voted to allow wrongdoers to settle for no restitution, no forfeiture of ill-gotten gains, no admission or findings of liability, and no notice to victims.[3] In adopting this rule, the Commission acknowledges that this longstanding policy was misguided and agrees that the codification of today's final rule is long overdue.

Noteworthy Provisions of the Final Rule

In 2019, *TINA.org* filed a petition with the Commission to promulgate a rule, given the rampant Made in USA fraud across sectors of the economy. In 2020, the Commission issued a Notice of Proposed Rulemaking and then analyzed a substantial number of comments from producers, consumers, foreign governments, and others.[4] After considering these comments, the Commission has adopted a rule consistent with the authority granted by Congress in 1994. There are several aspects worthy of brief discussion.

First, the Commission has codified the ''all or virtually all'' standard, consistent with the FTC's longstanding Enforcement Policy Statement on U.S. Origin Claims.[5] This standard covers *unqualified* claims. The Commission must protect the public from deception, and the agency declines to adopt alternative approaches, as explained in the final rule.

Second, the Commission has outlined a definition of ''label'' consistent with the Commission's expertise on labeling. While the Commission declines to adopt a definition that includes a list of specific examples, such as restaurant menus, the definition of label does extend beyond labels physically affixed to a product. As described in the rule, other depictions of labels are also covered; in some circumstances, labels appearing online may also be subject to the rule.[6] The Commission declines to cover advertising more broadly, as this is inconsistent with the authority granted by Congress.

Third, there was considerable interest in the rulemaking from farmers, ranchers, and others in the meat and agricultural industry, with the majority of comments arguing in favor of stricter standards. The rule declines to grant an exemption sought by the meatpacking industry, as this would be inconsistent with the Commission's authority prescribed by Congress under the Packers and Stockyards Act.[7] However, contemporaneous with the FTC's vote today, the U.S. Department of Agriculture has announced that it will be conducting a top-to-bottom review of its labeling standard. USDA has previously acknowledged that its

[1] *See* 15 U.S.C. 45a.

[2] *See generally* Statement of Commissioner Rohit Chopra Regarding Activating Civil Penalties for Made in USA Fraud (Apr. 17, 2019), *https://www.ftc.gov/public-statements/2019/04/statement-commissioner-rohit-chopra-regarding-activating-civil-penalties.*

[3] Even without a final rule, Commissioners could have sought more in administrative settlements, given that much of the Made in USA fraud detected by Commission staff met the definition of ''dishonest or fraudulent'' in Section 19 of the FTC Act. 15 U.S.C. 57b. Instead, Commissioners routinely accepted settlements with no meaningful relief at all.

[4] The Commission received over 700 comments in response to its Notice of Proposed Rulemaking on Made in USA labeling. *See FTC Seeks Comments on MUSA Rulemaking, Matter No. P074204,* Docket ID FTC–2020–0056 (July 16, 2020), *https://www.regulations.gov/docket/FTC-2020-0056.*

[5] *See* ''Made in USA'' and Other U.S. Origin Claims, 62 FR 63756 (Dec. 2, 1997).

[6] *See* 16 CFR 323.3.

[7] *See* 7 U.S.C. 227.

''Product of USA'' designation may be deceptive. I am extremely grateful to Secretary Tom Vilsack and USDA staff for the action they are taking.

I hope the USDA will study the FTC's rulemaking record carefully and come to the same conclusion I have: The USDA's Product of USA standard is misleading and distorts competition in the retail market for beef and other products. I also believe that unqualified ''Product of USA'' claims for meat products are only appropriate when the animal was born, raised, and slaughtered in the United States. Given our shared jurisdiction, I expect that the Commission will deepen its partnership with the USDA and closely coordinate on any enforcement proceeding with respect to retail sales of meat and other products.

Conclusion

The Commission appreciates the substantial public interest in protecting the Made in USA brand. The final rule provides substantial benefits to the public by protecting businesses from losing sales to dishonest competitors, and protecting families seeking to purchase American-made goods. More broadly, this long-overdue rule is an important reminder that the Commission must do more to use the authorities explicitly authorized by Congress to protect market participants from fraud and abuse. I thank my fellow Commissioners and members of the Commission staff who contributed to the development of this final rule, as well as members of the public for their thoughtful contributions.

Appendix II: Dissenting Statement of Commissioner Christine S. Wilson

Today the Commission announces a Final Rule with respect to ''Made in USA'' (MUSA) labels. I support the FTC's prosecution of MUSA fraud [1] and supported its consideration of a rule that addresses deceptive MUSA claims on labels, consistent with the authority granted to the FTC by Congress in Section 45a. The Rule announced today, however, exceeds that authority.

Section 45a of the FTC Act—the provision pursuant to which we advance this Rule—authorizes the Commission to issue rules governing MUSA claims on products ''with a 'Made in the U.S.A.' or 'Made in America' label, or the equivalent thereof.'' The provision is titled ''Labels on products'' and repeatedly references ''labels.'' The Commission nonetheless has chosen to promulgate a rule that could be read to cover all advertising, not just labeling.

This Rule is not supported by the plain language of 45a. It is clear Congress intended to extend rulemaking authority over the many potential variations (or ''equivalents'') of ''Made in the U.S.A.'' or ''Made in America'' claims that may be found on labels, not labels and claims made in advertising or marketing. The legislative history for Section 45a supports this interpretation. Specifically, the Conference Report on H.R. 3355 discusses any label characterizing ''a product as 'Made in the U.S.A.' or the equivalent thereof,'' signaling Congress' intent that the statute should cover not just literal invocations of ''Made in the U.S.A.,'' but also equivalents to that claim (*i.e.,* Made in America, American Made, and so on).[2]

The Commission's Rule defines the term far more broadly than any FTC precedent, and in a way that, in my view, exceeds our statutory grant of rulemaking authority.[3] The Rule we issue today will cover not just labels, but all:

> ''materials, used in the direct sale or direct offering for sale of any product or service, that are disseminated in print or by electronic means, and that solicit the purchase of such product or service by mail, telephone, electronic mail, or some other method without examining the actual product purchased'' [4] that include ''a seal, mark, tag, or stamp labeling a product Made in the United States.'' [5]

This language could bring within the scope of the Rule stylized marks in online advertising or paper catalogs and potentially other advertising marks, such as hashtags, that contain MUSA claims.[6]

In the statement I issued when the Commission sought comment on this proposed Rule, I noted that were Congress drafting this statute now, it might choose language to encompass those broader contexts, including online advertising.[7] But there was no plausible argument to be made that the ordinary meaning of the text when enacted in 1994 encompassed online advertising—a period when online shopping was largely unfamiliar to most consumers.[8] As it happens, the Senate recently passed the Country of Origin Labeling Online Act (COOL Act), which prohibits deceptive country-of-origin representations. There Congress did, in fact, specify its application to labeling as well as other forms of online advertising:

> it shall be unlawful to make any false or deceptive representation that a product or its parts or processing are of United States origin in any labeling, advertising, or other promotional materials, or any other form of marketing, including marketing through digital or electronic means in the United States.[9]

This language, in contrast to Section 45a, leaves no doubt it applies to labeling *and* advertising and confirms Congress views ''labeling'' as distinct from ''advertising or other promotional materials,'' including in an online context.

To the extent the Commission seeks to issue a broader prohibition on Made in USA fraud, as Commissioner Chopra asserted when the Commission sought comment on this Rule, it has other options. The Commission can institute a rulemaking proceeding pursuant to Section 18 of the FTC Act. Several commenters suggested that rather than promulgate a limited rule for labeling claims, the Commission should conduct a full proceeding to address all advertising claims.[10] The Commission has not taken this action. The Commission alternatively could work with Congress to effectuate the passage of the COOL Act, which would appear to moot this Rule if enacted.

Accordingly, because this Rule exceeds the scope of authority granted by Congress to the FTC, I dissent. I do not support creatively and expansively interpreting the agency's jurisdiction with respect to rulemaking authority.

The Commission, for more than 80 years, built a comprehensive program to ensure

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[1] I have voted to support every MUSA enforcement action recommended to the Commission by staff since joining the Commission. *See* In the Matter of Gennex Media, LLC No. C–4741 (Apr. 2021), *https://www.ftc.gov/system/files/documents/cases/2023122gennexmediafinalorder.pdf;* In the Matter of Chemence, Inc., *et al.,* No. 4738 (Feb. 2021), *https://www.ftc.gov/system/files/documents/cases/2021-02-10_chemence_admin_order.pdf;* In the Matter of Williams-Sonoma, Inc., No. C–4724 (July 2020), *https://www.ftc.gov/system/files/documents/cases/2023025c4724williamssonomaorder.pdf;* U.S. v. *iSpring Water Systems, LLC, et al.,* No. 1:16–cv–1620–AT (N.D. Ga. 2019); *https://www.ftc.gov/system/files/documents/cases/172_3033_ispring_water_systems_-_stipulated_order.pdf;* In the Matter of Sandpiper Gear of California, Inc. *et al.,* No. 182–3095, *https://www.ftc.gov/enforcement/cases-proceedings/182-3095/sandpiper-california-inc-et-al-matter;* Underground Sports d/b/a Patriot Puck, et al., No. 182–3113 (April 2019), *https://www.ftc.gov/enforcement/cases-proceedings/182-3113/underground-sports-inc-doing-business-patriot-puck-et-al;* In the Matter of Nectar Sleep, LLC, No.182–3038 (Sept. 2018), *https://www.ftc.gov/enforcement/cases-proceedings/182-3038/nectar-brand-llc.*

[2] Conf. Rep. on H.R. 3355 (filed in House (8/21/1994)).

[3] Several commenters echoed the concerns I raised in my statement when the Commission sought comment on this proposed Rule and those raised by Commissioner Phillips. *See* Council for Responsible Nutrition Comment; Personal Care Products Council Comment; National Association of Manufacturers Comment; Anonymous Comment 592.

[4] *See* Part 323.1(b).

[5] *See* Part 323.3.

[6] Guidance on the definition of ''label'' can be found in analogous FTC rules and guides in a variety of contexts. There, ''labels'' repeatedly have been defined as a distinct subcategory of advertising (in other words, not coterminous with advertising)1 and have been described as objects attached to a product or its packaging.1 Given both the statutory guidance Congress provided when it drafted this statute, and precedent concerning the term ''label'' in FTC rules and guides, the Commission has ample landmarks to draft a Rule that falls within its jurisdictional boundaries.

[7] Statement of Commissioner Christine S. Wilson Concurring in Part, Dissenting in Part, Notice of Proposed Rulemaking related to Made in USA Claims (June 22, 2020), *https://www.ftc.gov/system/files/documents/public_statements/1577099/p074204musawilsonstatementrev.pdf.*

[8] Report: Americans Going Online . . . Explosive Growth, Uncertain Destinations, Pew Research Center (Oct. 16, 1995) (noting ''most consumers are still feeling their way through cyberspace . . . [and] have yet to begin purchasing goods and services online''), available at: *https://www.people-press.org/1995/10/16/americans-going-online-explosive-growth-uncertain-destinations/.*

[9] U.S. Innovation and Competition Act, S. 1260, Section 2510, 117th Cong. (June 8, 2021), *https://www.democrats.senate.gov/imo/media/doc/DAV21A48.pdf.*

[10] *See* UIUC Accounting Group Comment; Shirley Boyd Comment; UIUC—BADM Comment; Senators Comment; United Steelworkers Comment; Women Involved in Farm Economics/Pam Potthoff Beef Chairman Comment.

consumers can trust ''Made in the USA'' claims.[11] My colleagues believe the Commission's 80 year MUSA enforcement program was a failure and only a rule and the imposition of penalties will deter false MUSA claims. I believe administrative consents, which were an integral part of this program, can be an appropriate remedy to address deceptive MUSA claims, consistent with the views of bipartisan Commissions during the last 25 years. I support seeking monetary relief where appropriate but cannot support acting outside the constraints of our legislative authority.[12]

I fear as well this Commission's desire to promulgate or utilize our regulatory authority in ways that exceed the boundaries of underlying statutes and corresponding Congressional intent will continue. The Supreme Court's recent decision in *AMG*[13] has eliminated the FTC's ability to seek equitable monetary relief under Section 13(b) of the FTC Act to compensate consumers. Thus, the temptation to test the limits of our remaining sources of authority is strong. I urge my colleagues to pause. Previous FTC forays into areas outside its jurisdictional authority have resulted in swift condemnation from the courts and Congress.[14] Expansive interpretations of our rulemaking authority will not engender confidence among members of Congress who have in the past expressed qualms about the FTC's history of frolics and detours.[15]

[FR Doc. 2021–14610 Filed 7–13–21; 8:45 am]

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[11] The FTC has issued over 150 closing letters to companies making misleading U.S.-origin claims. Made in USA Workshop Report at 3 (June 2020). Companies only receive closing letters if they demonstrate to staff they will come into compliance with the FTC's Enforcement Policy Statement on ''Made in the USA.'' The staff's workshop report explains ''companies often produce substantiation for updated claims to the FTC staff, and then present a plan that includes training staff, updating online marketing materials (*e.g.,* company websites and social media platforms), updating hardcopy marketing materials (*e.g.,* product packaging, advertisements, tradeshow materials), and working with dealers, distributors, and third-party retailers to ensure downstream claims are in compliance.'' *Id.* at 3 n.7. The FTC has also settled over 25 enforcement actions, charging that companies refused to come into compliance or engaged in outright fraud. *Id.*

[12] I would note as well that seeking civil penalties for deceptive MUSA claims, as defined under the Commission's Rule, could have adverse market effects. Excessive penalties, divorced from harm, can result in over-deterrence. Importantly, the costs associated with over-deterrence are likely to increase with the expansiveness of the definition of labelling.

[13] *AMG* v. *FTC*, slip op No. 19–508 (Apr. 22, 2021), *https://www.supremecourt.gov/opinions/20pdf/19-508_l6gn.pdf.*

[14] *See* Federal Trade Commission Improvements Act of 1980, Public Law 96–252, 94 Stat. 374 (1980) (reforming the ability of the FTC to promulgate rules by requiring a multi-step process with public comment and subject to Congressional review). This Act also authorized $255 million in funding for the Commission and was the first time since 1977 the agency was funded through the traditional funding process after the backlash from Congress over its rulemaking activities. *See* Kintner, Earl, *et al.,* ''The Effect of the Federal Trade Commission Improvements Act of 1980 on the FTC's Rulemaking and Enforcement Authority,'' 58 Wash. U. Law Rev. 847 (1980); *see also* J. Howard Beagles III and Timothy J. Muris, FTC Consumer Protection at 100: 1970s Redux or Protecting Markets to Protect Consumers?, 83 Geo. Wash. L. Rev. 2157 (2015) (describing the ''disastrous failures'' of the FTC in the 1970s and the 1980s from enforcement and regulatory overreach and quoting Jean Carper, The Backlash at the FTC, Wash. Post, C1 (Feb. 6, 1977) (describing the backlash from Congress at the FTC, after a period of intense rulemaking activity culminating in the agency's being dubbed the ''National Nanny'')); *see also* Alex Propes, Privacy and FTC Rulemaking: A Historical Context, IAB (Nov. 6, 2018) (discussing how the FTC's rulemaking history could be influencing Congressional comfort with vesting the FTC with additional privacy authority), *https://www.iab.com/news/privacy-ftc-rulemaking-authority-a-historical-context/.*

[15] *See* Transcript: Oversight of the Federal Trade Commission: Strengthening Protections for Americans' Privacy and Data Security (May 8, 2019), *available at: https://docs.house.gov/meetings/IF/IF17/20190508/109415/HHRG-116-IF17-Transcript-20190508.pdf.* At this Hearing, Rep. McMorris Rogers stated: ''In various proposals, some groups have called for the FTC to have additional resources and authorities. I remain skeptical of Congress delegating broad authority to the FTC or any agency. However, we must be mindful of the complexities of this issue as well as the lessons learned from previous grants of rulemaking authority to the Commission.'' Transcript at 8–9. Rep. Walden similarly stated: ''it has been a few decades, but there was a time when the FTC, as we heard, was given broad rulemaking authority but stepped past the bounds of what Congress and the public supported. This required further congressional action and new restrictions on the Commission.'' Transcript at 62.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. FDA–2020–F–1289]

Food Additives Permitted in Feed and Drinking Water of Animals; Selenomethionine Hydroxy Analogue

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA, we, or the Agency) is amending the regulations for food additives permitted in feed and drinking water of animals to provide for the safe use of selenomethionine hydroxy analogue as a source of selenium in feed for beef and dairy cattle. This action is in response to a food additive petition filed by Adisseo France S.A.S.

DATES: This rule is effective July 14, 2021. See section V of this document for further information on the filing of objections. Submit either electronic or written objections and requests for a hearing on the final rule by August 13, 2021.

ADDRESSES: You may submit objections and requests for a hearing as follows. Please note that late, untimely filed objections will not be considered. Electronic objections must be submitted on or before August 13, 2021. The *https://www.regulations.gov* electronic filing system will accept objections until 11:59 p.m. Eastern Time at the end of August 13, 2021. Objections received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic objections in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting objections. Objections submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your objection will be made public, you are solely responsible for ensuring that your objection does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your objection, that information will be posted on *https://www.regulations.gov.*
- If you want to submit an objection with confidential information that you do not wish to be made available to the public, submit the objection as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper objections submitted to the Dockets Management Staff, FDA will post your objection, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2020–F–1289 for ''Food Additives Permitted in Feed and Drinking Water