Other agencies have worked on this topic...



FDA identifies certain seafood origin claims that are not misbranded under the FDCA (in FDA's opinion)



FDA even provided sample graphics!

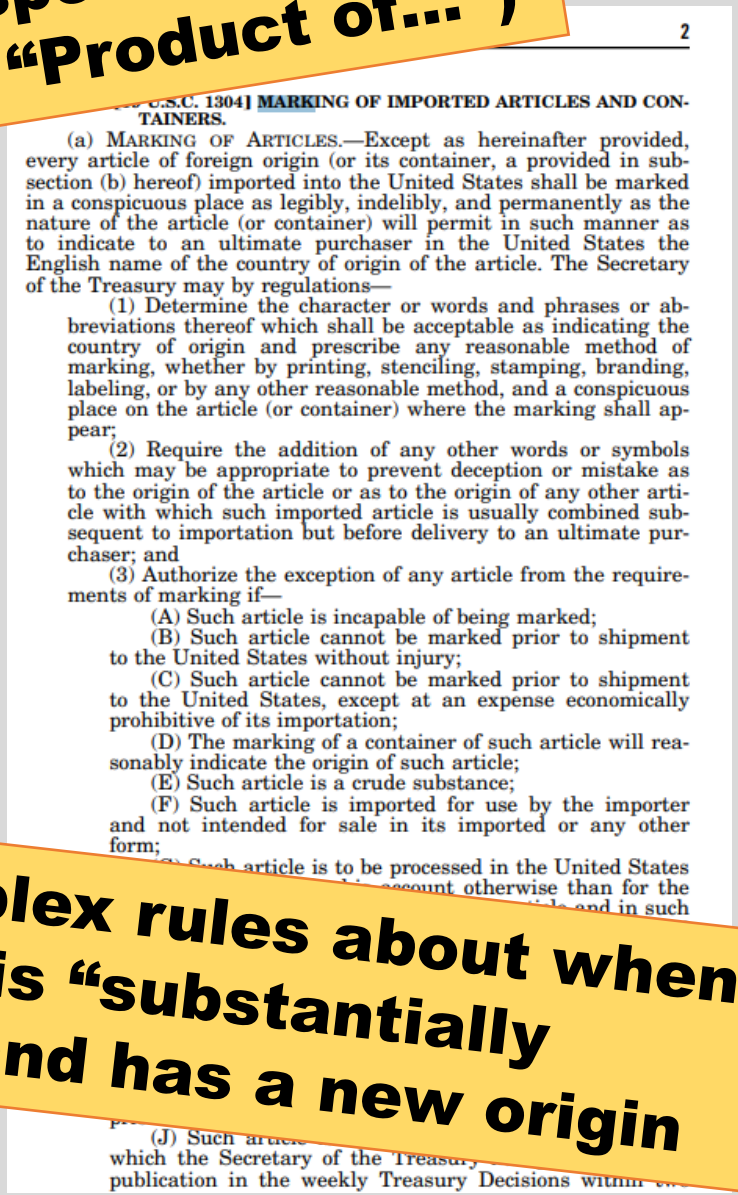
Origin claims are highly regulated ... but primarily by other agencies







Customs is responsible for "marking" (think "Product of...")



2

U.S.C. 1304] MARKING OF IMPORTED ARTICLES AND CONTAINERS.

(a) MARKING OF ARTICLES.—Except as hereinafter provided, every article of foreign origin (or its container, a provided in subsection (b) hereof) imported into the United States shall be marked in a conspicuous place as legibly, indelibly, and permanently as the nature of the article (or container) will permit in such manner as to indicate to an ultimate purchaser in the United States the English name of the country of origin of the article. The Secretary of the Treasury may by regulations—

(1) Determine the character or words and phrases or abbreviations thereof which shall be acceptable as indicating the country of origin and prescribe any reasonable method of marking, whether by printing, stenciling, stamping, branding, labeling, or by any other reasonable method, and a conspicuous place on the article (or container) where the marking shall appear;

(2) Require the addition of any other words or symbols which may be appropriate to prevent deception or mistake as to the origin of the article or as to the origin of any other article with which such imported article is usually combined subsequent to importation but before delivery to an ultimate purchaser; and

(3) Authorize the exception of any article from the requirements of marking if—

(A) Such article is incapable of being marked;

(B) Such article cannot be marked prior to shipment to the United States without injury;

(C) Such article cannot be marked prior to shipment to the United States, except at an expense economically prohibitive of its importation;

(D) The marking of a container of such article will reasonably indicate the origin of such article;

(E) Such article is a crude substance;

(F) Such article is imported for use by the importer and not intended for sale in its imported or any other form;

article is to be processed in the United States account otherwise than for the and in such

(J) Such
which the Secretary of the Treasury
publication in the weekly Treasury Decisions within

There are complex rules about when an article is "substantially transformed" and has a new origin

USDA's AMS is responsible for Country of Origin Labeling (COOL)

Covered Commodity	Country of Origin	Regulatory Text Citation	Conditions	Examples of Acceptable Labeling Terms
Farm Raised Fish and Shellfish	**U.S.**	7 CFR 60.128 (c)	1. Hatched, raised, harvested, & processed in the U.S. and ; 2. No substantial transformation outside the U.S.	**"Product of the U.S.(A)" "U.S.(A)"**
Wild Fish and Shellfish	**U.S.**	7 CFR 60.128 (d)	1. Harvested in U.S. waters or by a U.S. vessel and; 2. Processed in the U.S. or aboard a U.S. vessel and ; 3. No substantial transformation outside the U.S.	**"Product of the U.S.(A)" "U.S.(A)"**
Farm Raised Fish and Shellfish	**Imported**	7 CFR 60.200 (f)	Imported products that have NOT undergone substantial transformation in the U.S.	**As declared by U.S. Customs and Border Protection (CBP)**
Farm Raised & Wild Fish and Shellfish	**Imported**	7 CFR 60.200 (g)	Imported products which HAVE undergone substantial transformation in the U.S.	**"From Country X, Processed in the U.S." or;** **"Product of Country X and the U.S.(A)"**
Farm Raised & Wild Fish and Shellfish	**Commingled**	7 CFR 60.200 (h) (1)	1. Imported products NOT substantially transformed in the U.S., plus; 2. Other imported products NOT substantially transformed in the U.S. and/or with; 3. Products of U.S. origin and/or with; 4. Imported products that HAVE been substantially transformed in the U.S.	**Declaration shall indicate countries of origin in accordance with existing Federal requirements.**
Farm Raised & Wild Fish and Shellfish	**Commingled**	7 CFR 60.200 (h) (2)	1. Imported products that HAVE been substantially transformed in the U.S. plus; 2. Other imported products that HAVE been substantially transformed in the U.S., and/or with; 3. Product of U.S. origin	**Declaration shall indicate countries contained therein or may be contained therein.**

They piggy-back off Customs

FTC regulates “Made in USA”*

…principal inspector, …g 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 …ation (NARA). For information on …material at NARA, …https://

BILLING CODE …

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 …ule 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]

[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 …ficant minority of reasonable consumers is … *FTC* v. *Stefanchik*, 559 F.3d … was not required …”).

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 …S. Origin Claims* (the “Policy Statement”) …r research and public comment, …ally all” principle. Specifically, …ent provides a marketer making an … for its product should, at the time …tion, have a reasonable basis for …virtually all” of the product is …ted States. FTC, *Issuance of …licy Statement on “Made in USA” … Origin Claims*, 62 FR 63756, 63766

*Though for seafood they consider AMS the lead agency (see comment on page 37030)

FDA seems to have forgotten that these other agencies exist given they're never mentioned in the draft



They also seem to forget that there's already a general guidance on origin statements

CPG Sec. 560.200 Country of Origin Labeling

BACKGROUND:

A statement of the country of origin on the labeling of imported foods is not required by the Federal Food, Drug, & Cosmetic Act. This is a requirement of the U.S. Customs *and Border Protection (CBP)* as authorized by the Tariff Act of 1930 and CPB regulations (19 USC 1304(a) and 19 CFR Part 134).

And the plan to defer to other agencies

FDA's policy regarding false or misleading country of origin labeling is to defer to *CBP*. Such labeling is also a violation of the Tariff Act of 1930, which is enforced by *CBP*, and *CBP* can generally deal with this problem more efficiently than FDA.

REGULATORY ACTION GUIDANCE:

Information acquired by FDA personnel regarding false or misleading country of origin labeling should be transmitted by the Program Field Office to the local *CBP* office for their consideration, together with offers of FDA cooperation in the matter and a request that the field office be advised of any regulatory follow-up by *CBP*.

Let's not forget that a court in a consumer class action may largely ignore FDA's opinion



It is unclear when this guidance, which was not on FDA's To Do List, may be finalized.

One should also seriously question its weight given that this topic is primarily handled by other agencies, and a guidance such as this has minimal value for preemption purposes.



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LinkedIn:
John Johnson

jfjohnson@shb.com

FDAStorytime.com

