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Legal Issues Associated with FDA Standards of Identity: In Brief

name redacted
Legislative Attorney

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Summary

Standards of identity for foods overseen by the Food and Drug Administration (FDA) generally define the composition of a food, prescribing both mandatory and optional ingredients and fixing the relative proportions of each ingredient. This report addresses the following legal issues associated with the promulgation and enforcement of standards of identity for foods.

- Section 401 of the Federal Food, Drug, and Cosmetic Act (FFDCA) establishes the legal authority for the FDA to promulgate standards of identity for food. According to this statutory authority, a standard of identity for a particular food is necessary if such a standard would "promote honesty and fair dealing in the interest of consumers."
- Congress first authorized the promulgation of standards of identity for foods in 1938 in response to the failure of the federal government's enforcement actions to regulate "imitation" foods.
- The FDA creates standards of identity for food through the rulemaking process. The FDA or an interested person via a citizen petition may propose a standard of identity for adoption. After the FDA publishes the proposed standard of identity in the *Federal Register*, members of the public may submit objections and demand a public hearing. The standard of identity is effective once the FDA publishes the final order in the *Federal Register*. The FDA's promulgation of a final standard of identity constitutes a final agency action that is eligible for judicial review.
- The FDA enforces standards of identity through the misbranding provision in the FFDCA, which states that a food is misbranded if "it purports to be or is represented as" a food for which the FDA has established a standard of identity and deviates from that standard. Once the agency deems a food to be misbranded under this provision, then the agency can exercise various enforcement options.

Congress generally has not modified FDA's authority for promulgating standards of identity. However, Congress has introduced legislation calling for the FDA to promulgate standards for specific foods. For example, the Trade Facilitation and Trade Enforcement Act of 2015 (H.R. 644, S. 1269) of the 114th Congress includes a provision to encourage a standard of identity for honey.

Contents

Contacts

Section 401 of Federal Food, Drug and Cosmetic Act (FFDCA) grants the Food and Drug Administration (FDA) the authority to promulgate regulations that create "standards of identity" for certain foods.[1] These standards establish the composition of the food, including mandatory and optional ingredients. Industry participants who do not follow the standard of identity for a particular food may be liable for misbranding under the FFDCA, which could lead to FDA enforcement action.[2] FDA creates standards of identity through the administrative rulemaking process, with opportunity for public notice and comment. While Congress has not modified FDA's authority for promulgating standards of identity, it has called for FDA to promulgate specific standards for certain foods. For example, the proposed Trade Facilitation and Trade Enforcement Act of 2015 (H.R. 644) includes a provision that would encourage a standard of identity for honey.[3]

This report discusses various legal issues related to food standards of identity. These issues include the legal authority for the FDA to promulgate regulations creating standards of identity, FDA's administrative rulemaking process to create standards of identity, and FDA's enforcement of these standards. This report also provides an overview of related legislation in the 114th Congress.

FDA Standards of Identity

A standard of identity establishes the composition of a food, including mandatory and optional ingredients, and fixes the amounts or relative proportions of each ingredient or a specific method of manufacture.[4] Congress intended that standards of identity would resemble "recipes" for specific foods.[5] These standards of identity seek to prohibit economic adulteration and mislabeling of food by providing consumers with the "assurance that they will get what they may reasonably expect to receive."[6]

Section 401 of the FFDCA provides the primary statutory authority for the FDA to promulgate standards of identity for food via regulation. The provision states that

> [w]henever in the judgment of the Secretary such action will promote honesty and fair dealing in the interest of consumers, he shall promulgate regulations fixing and establishing for any food, under its common or usual name so far as practicable, a reasonable definition and standard of identity, a reasonable standard of quality, and/or reasonable standards of fill of container.[7]

Thus, an appropriate standard of identity for a particular food is one that "will promote honesty and fair dealing in the interest of consumers."[8]

Once the FDA creates a standard of identity, no product that fails to meet the composition requirements of that standard may be marketed under the name the FDA has appropriated to that particular standard. Section 403(g) of the FFDCA states that the FDA shall deem a food

[1] 21 U.S.C. § 341.

[2] 21 U.S.C. § 343(g).

[3] H.R. 644, 114th Cong., 2d Sess.

[4] 21 U.S.C. § 341.

[5] H. Rept. 75-2139, p 2.

[6] Fed. Sec. Adm'r v. Quaker Oats Co., 318 U.S. 218, 232 (1943).

[7] 21 U.S.C. § 341.

[8] *Id.*

misbranded if "it purports to be or is represented as" a food for which the FDA has established a standard of identity and whose composition deviates from the standard.[9]

After the enactment of the Nutrition Labeling and Education Act (NLEA),[10] the FDA promulgated regulations that allow for the addition of safe and suitable[11] ingredients to a "standardized" food.[12] Under these regulations, a manufacturer may refer to the adapted standardized food by the nutrient content claim and the original standardized food term.[13] For example, under FDA regulations, a manufacturer may use safe and suitable artificial sweeteners that are not expressly listed in a particular standard of identity. According to the FDA, these regulations "assist consumers in maintaining healthy dietary practices by providing for a modified version of a traditional standardized food to achieve a nutritional goal ... [while maintaining] a descriptive name that is meaningful to consumers."[14] The FDA relies on concepts like "safe and suitable" when regulating food to allow for technological flexibility with food development. Permitting such flexibility, according to the FDA, encourages oversight of food "without adversely affecting the characteristics of food" and "minimizes any future amendment of the standards for additional specific ingredients."[15]

The FDA also adopts food standards established by the Codex Alimentarius Commission, formed by the World Health Organization and the Food and Agriculture Organization of the United Nations.[16] The Codex Alimentarius is a collection of international recognized food standards and guidelines promoting food safety.[17] The FDA publishes these food standards in the *Federal Register* for public review and comment before accepting the standard with or without any changes.[18]

Legislative History of Section 401

Congress first authorized the promulgation of standards of identity for foods with the Federal Food, Drug, and Cosmetic Act of 1938.[19] The Pure Food and Drugs Act of 1906,[20] the predecessor of the 1938 act, did not provide the legal authority for the government to promulgate such food standards, leaving the federal government with limited oversight of "imitation"

[9] 21 U.S.C. § 343(g).

[10] P.L. 101-535.

[11] 21 C.F.R. § 130.3 defines "safe and suitable" as an ingredient that "(1) Performs an appropriate function in the food in which it is used. (2) Is used at a level no higher than necessary to achieve its intended purpose in that food. (3) Is not a food additive or color additive as defined in section 201 (s) or (t) of the Federal Food, Drug, and Cosmetic Act as used in that food, or is a food additive or color additive as so defined and is used in conformity with regulations established pursuant to section 409 or 721 of the act."

[12] 21 C.F.R. § 130.10.

[13] For example, a manufacturer may refer to a product as "low-calorie mayonnaise" when the product contains additional ingredients that lower the caloric total as compared to the standardized mayonnaise.

[14] Artificially Sweetened Fruit Jelly and Artificially Sweetened Fruit Preserves and Jams; Proposed Revocation of Standards of Identity, 77 Fed. Reg. 71746 (Dec. 4, 2012).

[15] Cultured and Acidified Buttermilk, Yogurts, Cultured and Acidified Milks, and Eggnog; Proposal to Establish New Identity Standards, 42 Fed. Reg. 29920 (June 10, 1977).

[16] 21 C.F.R. § 130.6.

[17] *See* "CODEX ALIMENTARIUS; International Food Standards," *available at* http://www.fao.org/fao-who-codexalimentarius/en/.

[18] 21 C.F.R. § 130.6.

[19] P.L. 75-717, § 401.

[20] P.L. 59-384.

products. During the 1920s and 1930s, the U.S. government brought adulteration and misbranding claims under the 1906 act against a product called "Bred Spred," a fruit product containing 20% fruit.[21] The government claimed that consumers regarded the product as jam, but the product did not have the 45% fruit content generally associated with jam.[22] The manufacturer argued that Bred Spred was not misbranded as it did not purport to be jam.[23] The courts agreed with the manufacturer, holding that the product was not misbranded under the 1906 act because the government did not offer any evidence of false or misleading statements on the label.[24] For the court, the imitation of a product was not sufficient evidence of misbranding under the act.[25]

Leading up to the passage of the 1938 act, Congress faced concerns about products such as Bred Spred and the potential fraud and the subsequent loss of consumer confidence that may follow from the purchase of similar foods. According to the legislative history of the 1938 act, Congress primarily authorized the creation of standards of identity as a regulatory tool "under which the integrity of food products can be effectively maintained."[26] During the passage of the 1938 act, Congress acknowledged that "one great weakness in the present food and drugs law [1906 Act] is the absence of authoritative definitions and standards of identity."[27] Referring to the Bred Spred cases, the House report for the 1938 act stated that "the government repeatedly has had difficulty in holding such articles as commercial jams and preserves and many other foods to the time-honored standards employed by housewives and reputable manufacturers."[28] The report also claimed that the government lost these cases because the courts held that these "home" standards are not legally binding under existing law.[29] Thus, Congress intended that the authorization of standards of identity would "meet[] the demands of legitimate industry[,]... [would] effectively prevent the chiseling operations of the small minority of manufacturers, [would] in many cases expand the market for agricultural products, particularly for fruits, and finally [would] insure fair dealing in the interest of the consumer."[30] The Supreme Court has interpreted this legislative history as Congress's recognition of the inability of consumers to determine the relative merits of similar products solely on the basis of the labeling information.[31]

Regulatory Process for Adoption of Food Standards

The FDA promulgates standards of identity for food through the rulemaking process. The formal rulemaking procedure followed by the FDA in adopting a standard of identity can be organized into three stages.[32] First, the FDA[33] or any "interested person" via a citizen petition[34] may propose

[21] *See, e.g.*, U.S. v. Ten Cases, More or Less, of Bred Spred, 49 F.2d 87 (8th Cir. 1931); U.S. v. Forty-Nine and One-Half Cases of Bred Spred (E.D. Mich. 1927).

[22] *Bred Spred*, 49 F.2d at 89.

[23] *Id.* at 90.

[24] *Id.*

[25] *Id.*

[26] H. Rept. 75-2139, p 2.

[27] *Id.* at 5.

[28] *Id.*

[29] *Id.*

[30] *Id.*

[31] *Quaker Oats*, 318 U.S. at 230-31. The case *Federal Security Administrator v. Quaker Oats. Co.* served as the Supreme Court's first review of FDA's authority to promulgate standards of identity.

[32] Generally, the FDA process follows the administrative rulemaking procedure outlined in the Administrative Procedure Act (See 5 U.S.C. § 551 et seq.).

a standard of identity for adoption.[35] A private petitioner must state "reasonable grounds" for the proposal in order for the FDA to publish the order and proceed with the process. Thus, a successful petition must assert provable facts demonstrating that the proposal, if adopted, "would promote honesty and fair dealing in the interest of consumers."[36] The petitioner must also assert that he commits himself to substantiate the information in the petition with additional evidence in a public hearing, if such a hearing becomes necessary.[37] If the proposal satisfies this requirement, the FDA publishes the proposal in the *Federal Register* as a "Notice of Proposed Rulemaking," and all interested persons are invited to file comments orally or in writing.[38] After the agency studies the public comments submitted, the agency can decide to reject the proposal or to accept the proposal by publishing an order.[39] The agency is not bound to issue the order within a specific timeframe after the comment period. Generally, the order, which establishes the standard of identity, is effective on the date specified in the order.

Within 30 days of the order's publication, the agency begins the second stage of the rulemaking process. During this stage, all persons adversely affected by the order may submit objections and demand a public evidentiary hearing to resolve disputed factual issues that the objections have raised.[40] The filing of such objections serves as a stay of the disputed provisions in the order, until the FDA takes final action.[41] The public hearing is open to all interested persons and is on the record.[42] The participants of the hearing may present documentary evidence and oral testimony and have the ability to cross-examine the witnesses.

Following the hearing, the final stage of the process involves the agency issuing a tentative order, including detailed findings of fact and conclusions upon which the order is based.[43] Any party of record may object to this proposed order and request an oral argument before the FDA. The FDA then publishes the final order setting forth the standard of identity.

Judicial Review

The FDA's final standard of identity constitutes a final agency action that is eligible for judicial review.[44] A party adversely affected by the standard of identity order may seek judicial review in the U.S. Court of Appeals for the circuit in which the party resides or has a principal place of

(...continued)

[33] For example, the FDA may promulgate a new standard of identity to comply with a directive from Congress in legislation.

[34] 21 C.F.R. § 10.30 outlines the format and content requirements for a citizen petition to the FDA.

[35] 21 U.S.C. § 371(e)(1).

[36] 21 U.S.C. § 371(e)(1); 21 U.S.C. § 341 (Provides the FDA with the legal authority to promulgate regulations to establish a standard of identity "whenever ... such action will promote honesty and fair dealing in the interest of consumers); 21 C.F.R. § 130.5(b)("Any petition for a food standard shall show that the proposal, if adopted, would promote honesty and fair dealing in the interest of consumers.")

[37] 21 C.F.R. § 130.5(c).

[38] 21 U.S.C. § 371(e)(1).

[39] *Id.*

[40] 21 U.S.C. § 371(e)(2).

[41] *Id;* 21 C.F.R. § 10.35.

[42] 21 U.S.C. § 371(e)(3).

[43] *Id.*

[44] 21 C.F.R. § 10.45.

business.[45] An adverse effect that is too remote or indirect generally does not provide a petitioner sufficient standing to petition a review of the order.[46]

Upon such a petition for judicial review, the court then has jurisdiction to affirm the order, or to set the order aside in whole or in part, temporarily or permanently. In reaching such a decision, the court considers whether the FDA's findings regarding the standard of identity order are supported by substantial evidence.[47] According to the FFDCA, the FDA's findings of fact relating to the particular standard up for review "if supported by substantial evidence ... shall be conclusive."[48] According to the Supreme Court, this scope of judicial review is appropriate for the review of "regulations of general application adopted by an administrative agency under its rulemaking power in carrying out the policy of a statute with whose enforcement it is charged."[49]

The Supreme Court reviewed the FDA's[50] authority to promulgate regulations fixing standards of identity in *Federal Security Administrator v. Quaker Oats Co.* In this case, the Quaker Oats Company petitioned for review of the standards of identity for farina, enriched farina, and other flour mill products.[51] The U.S. Court of Appeals for the Seventh Circuit set aside the standards of identity for these products, holding that the evidence on which the standards were based was "entirely speculative and conjectural" and would not justify the conclusion that such regulations would "promote honesty and fair dealing in the interest of consumers."[52] Furthermore, the Court of Appeals held that there was no evidence of consumer confusion to justify the particular standards for farina and enriched farina.[53]

The Supreme Court disagreed and upheld the standards of identity. The Court stated that the FFDCA does not permit courts to "substitute their own judgment" for that of the agency promulgating the standards, but Section 401 instead emphasizes that the standards of identity are based on the "judgment of the Administrator."[54] Thus, deferring to the Administrator[55] promulgating the standards, the Court concluded that there was sufficient evidence "to support the Administrator's judgment that, in the absence of appropriate standards of identity, consumer confusion would ensue."[56] Thus, the Supreme Court has concluded that the agency's determination, "if based on substantial evidence of record, and if within statutory and

[45] 21 U.S.C. § 371(f)(1).

[46] American Lecithin Co., v. McNutt, 155 F.2d 784, 786 (2d Cir. 1946)(Second Circuit found that a company that produces an ingredient that is an optional ingredient in the cacao product standard of identity was not sufficiently adversely affected to bring a petition as the company did not represent the cacao products industry and the order did not affect the petitioner's conduct of business).

[47] 21 U.S.C. § 371(f)(3).

[48] *Id.*

[49] *Quaker Oats*, 318 U.S. at 228 (internal citations omitted).

[50] At the time of the case the "Federal Security Administrator" promulgated the regulations for standards of identity and oversaw food and drug safety.

[51] *Quaker Oats*, 318 U.S. at 220.

[52] *Id.* at 223.

[53] *Id.* at 226.

[54] *Id* at 227.

[55] The Administrator cited in Section 401 of the FFDCA is currently the head of the FDA. In 1938, the Federal Security Agency had jurisdiction over food and drug safety in addition to other public health programs that are currently under the jurisdiction of the Department of Health and Human Services.

[56] *Quaker Oats*, 318 U.S. at 228-29.

constitutional limitations, is controlling even though the reviewing court on the same record might have arrived at a different conclusion."[57]

Rulemaking Procedures to Amend or Remove a Standard of Identity

In order to amend or to remove an existing standard of identity, the agency follows the same formal rulemaking procedures as it does when creating a new standard of identity. Amendments may include allowing a new ingredient or method of manufacture. The amendment process begins with the FDA or an interested person filing a petition to amend or to revoke the standard of identity.[58] Like the test for promulgating standard of identity regulations, a revocation or amendment of a standard must also promote honesty and fair dealing in the interest of consumers.[59]

FDA Enforcement of Standards of Identity

The FDA enforces standards of identity through the misbranding provision in the FFDCA (Section 403).[60] Once the agency deems a food to be misbranded under this provision, then the agency can exercise various enforcement options against the manufacturer or other industry representatives.

Misbranding

A food is deemed misbranded "[i]f it purports to be or is represented as a food for which a definition and standard of identity has been prescribed ... unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food."[61]

The FDA has not provided any formal guidance on when a product "purports to be" a food for which there is a standard of identity. In the past, the agency has read the "purports to be or is represented as" language broadly to challenge in a judicial enforcement action food that resembles in appearance, packaging, or taste, a food for which there is a standard of identity.[62] Courts have relied upon the ordinary meaning of "purport" as "to convey, imply, or press outwardly ... to have the appearance... of being, intending, claiming" when interpreting this statutory language.[63]

A court generally does not require evidence of consumer deception under this misbranding provision. For example, the U.S. government took enforcement action against food sold as

[57] *Id.* at 228.

[58] 21 C.F.R. § 10.25.

[59] 21 U.S.C. § 341.

[60] 21 U.S.C. § 343.

[61] 21 U.S.C. § 343(g).

[62] *See, e.g.*, Libby, McNeill & Libby v. U.S., 148 F.2d 71 (2d Cir.1945); U.S. v. Ninety-Nine Cases ... Southland Fountain Fruit, 89 F.Supp. 992 (E.D.Tenn.1949).

[63] U.S. v. 30 Cases, More or Less, Leader Brand Strawberry Fruit Spread, 93 F.Supp. 764, 769 (S. D. Iowa 1950)(citing Webster's New International Dictionary, 2d Ed.).

"tomato catsup with preservative."[64] The product did not conform to the standard of identity for catsup because it contained sodium benzoate. The Second Circuit concluded that the product at issue "purports to be tomato catsup" even though the manufacturer added "mere words of qualification or description."[65] For the court, the fact that this was "a product that looks, tastes, and smells like catsup, which caters to the market for catsup, which dealers bought, sold, ordered, and invoiced as catsup, without reference to the preservative, and which substituted for catsup on the tables of low priced restaurants" was sufficient evidence that the product violates the standard of identity for catsup, and thus was misbranded.[66] The court dismissed an alternate inquiry into "whether the ultimate purchaser will be misled" as an unnecessary approach in standards of identity cases.[67]

FDA Enforcement Actions

The FDA may exercise discretion in its enforcement of the misbranding provision for standards of identity, Section 403(g).[68] Thus, when the FDA finds that a food qualifies as misbranded under the FFDCA, the agency may then pursue several different enforcement options.[69] First, the FDA may issue a warning letter to alleged violators of the misbranding provision.[70] FDA warning letters are informal and advisory.[71] A warning letter may communicate the FDA position on a certain issue, but does not commit the agency to take any further enforcement action. Thus, the FDA has concluded that a warning letter does not qualify as a final agency action subject to judicial review under the Administrative Procedure Act.[72] The FDA may issue a warning letter for "minor violations of this [act] whenever [the agency] believes that the public interest [would] be adequately served by a suitable written notice or warning."[73] These warning letters give the recipients, such as manufacturers or other industry representatives, an opportunity to take voluntary corrective actions before the FDA initiates a more formal enforcement action.[74] The agency may favor a warning letter over other types of enforcement action as a more efficient enforcement option if the agency reasonably expects that the responsible firm or persons would take prompt corrective action after receiving such a letter.[75]

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[64] *Libby*, 148 F.2d at 71-72.

[65] *Id.* at 73.

[66] *Id.*

[67] *Id.*

[68] *See* Heckler v. Chaney, 470 U.S. 821, 835 (1985).

[69] For more information about FDA enforcement authority, see CRS Report R43794, *Food Recalls and Other FDA Administrative Enforcement Actions*, by (name redacted) and CRS Report R43927, *Food Safety Issues: FDA Judicial Enforcement Actions*, by (name redacted).

[70] For example, in August 2015, the FDA sent a warning letter to Hampton Creek Foods, the manufacturer of "Just Mayo" for misbranding violations under Section 403(g) of the FFDCA. For more information on this enforcement action, see CRS Legal Sidebar WSLG1386, *UPDATED: "Just Mayo" Just Isn't Warns FDA*, by (name redacted).

[71] FDA, Regulatory Procedures Manual, 4-1-1, *available at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/default.htm. It is important to note that the Regulatory Procedures Manual serves as a reference for FDA employees and industry. The manual is not binding on industry or the agency.

[72] 21 C.F.R. § 10.65(a).

[73] 21 U.S.C. § 336.

[74] Regulatory Procedures Manual, *supra* note 72, at 4-1-1.

[75] Regulatory Procedures Manual, *supra* note 72, at 4-1-3.

Under Section 304(a)(1) of the FFDCA, the government[76] may also seize a misbranded article of food in interstate commerce.[77] A seizure is a civil action used by the federal government when the removal of misbranded goods from interstate commerce is necessary to reduce consumer accessibility to those goods in order to protect public health.[78] Generally, a seizure includes two steps: the U.S. government's physical seizure of the adulterated or misbranded articles of food followed by the judicial condemnation proceeding. The U.S. district court where the article is found has jurisdiction over the seizure proceeding.[79] After a hearing on a seizure action, a district court may decree the "condemnation" of seized articles of food and order the destruction, sale, reconditioning, or export of such food.

Related Legislation in the 114th Congress

While Congress has not amended the FDA's legal authority to create standards of identity,[80] Congress has introduced legislation in the past to encourage FDA's promulgation of specific standards of identity. For example, the Trade Facilitation and Trade Enforcement Act of 2015 includes a provision declaring that it "is the sense of Congress that the Commissioner of Food and Drugs should promptly establish a national standard of identity for honey for the Commissioner responsible for U.S. Customs and Border Protection to use to ensure that imports of honey are (1) classified accurately and for purposes of assessing duties; and (2) denied entry into the United States if such imports pose a threat to the health or safety of consumers in the United States."[81] In support of this provision, Senator Gillibrand has stated the United States should adopt a national standard of identity for honey in order to protect consumers and to safeguard the integrity of honey products by preventing unscrupulous importers from flooding the market with misbranded honey products.[82] If such a provision becomes law, the FDA may then promulgate a standard of identity for honey through the administrative rulemaking process.

Author Contact Information

(name redacted)
Legislative Attorney

[76] For this type of judicial enforcement action, the FDA acts in conjunction with the Department of Justice.

[77] 21 U.S.C. § 334(a)(1).

[78] *See, e.g.*, U.S. v. 20 Cases, More or Less, Containing Buitoni 20% Protein Spaghetti, 130 F.Supp. 715 (D. Del. 1955)(U.S. government seized Buitoni Products shipped in interstate commerce. The products were advertised as spaghetti but did not conform to the standard of identity for that type of food).

[79] *Id.*

[80] Section 401 of the FFDCA has generally remained the same since its enactment in 1938, except for technical amendments in 1954 (68 Stat. 54), 1956 (70 Stat. 919), and 1993 (107 Stat. 776).

[81] H.R. 644, § 608(d); S. 1269, § 608(d).

[82] "Senators demand FDA reform for honey identity," Aug. 4, 2015, *available at* http://www.agri-pulse.com/Honey_Gillibrand_8042011.asp.