
RECENT REGULATION

HEALTH REGULATION — PATIENT PROTECTION AND AFFORDABLE CARE ACT — FOOD AND DRUG ADMINISTRATION FINALIZES REGULATIONS REQUIRING RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS TO LABEL CALORIES ON MENUS. — Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156 (Dec. 1, 2014) (to be codified at 21 C.F.R. pts. 11, 101).

Federal food-labeling laws enacted in the early 1990s exempted restaurants from nutrition-labeling requirements, but required the Food and Drug Administration (FDA) to define the term “restaurants or other establishments” in implementing the exemption.¹ In the Patient Protection and Affordable Care Act² (ACA), Congress expanded nutrition-labeling requirements to certain “restaurant[s] or similar retail food establishment[s] . . . with 20 or more locations,”³ again without defining “similar retail food establishment” or “locations.” Recently, the FDA finalized a menu-labeling rule that settles on a broad definition of “similar retail food establishment” to cover any establishment that sells “restaurant-type food.”⁴ Although the final rule’s broad definition of “similar retail food establishment,” which also expressly exempts schools,⁵ is legally permissible, the FDA acted on legally uncertain ground in exempting airplanes, trains, and food trucks through a surprising definition of “location.”⁶

On March 23, 2010, the ACA was signed into law, bringing federal nutrition-labeling requirements to restaurants for the first time.⁷ Sec-

¹ See Nutrition Labeling and Education Act of 1990, 21 U.S.C. § 343(q)(5)(A)(i) (2006) (amended 2010).

² Pub. L. No. 111-148, 124 Stat. 119 (2010) (codified as amended in scattered sections of 26 and 42 U.S.C.).

³ 21 U.S.C. § 343(q)(5)(H)(i) (2012).

⁴ Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 79 Fed. Reg. 71,156, 71,163 (Dec. 1, 2014) [hereinafter Menu Labeling Final Rule] (to be codified at 21 C.F.R. pts. 11, 101). The rule defines restaurant-type food to include things like sit-down and drive-through meals, take-out and delivery pizza, buffets, salad bars, and foods intended for individual consumption (like sandwiches at a deli counter). See *id.* at 71,170. Food that “consumers usually store for use at a later time or customarily further prepare,” such as a loaf of bread or deli meat, is not restaurant-type food. *Id.*

⁵ See *id.* at 71,169.

⁶ See *id.* at 71,171.

⁷ See CTR. FOR FOOD SAFETY & APPLIED NUTRITION, FOOD & DRUG ADMIN., FDA-2010-D-0370, DRAFT GUIDANCE FOR INDUSTRY: QUESTIONS AND ANSWERS REGARDING IMPLEMENTATION OF THE MENU LABELING PROVISIONS OF SECTION 4205 OF THE PATIENT PROTECTION AND AFFORDABLE CARE ACT OF 2010, at 4 (2010).

tion 4205 of the ACA⁸ requires certain “restaurants and similar retail food establishments . . . with 20 or more locations” to provide specified nutrition information for “standard menu item[s].”⁹ The ACA requires covered establishments to disclose the calorie content “in a clear and conspicuous manner” directly on the menu along with “a succinct statement concerning suggested daily caloric intake.”¹⁰ The law also requires that covered establishments make additional nutrition information — such as sodium content — available in written form, and the menu must include a notice that this additional nutrition information is available upon request.¹¹ The ACA set a deadline of March 23, 2011, for the FDA to issue implementing regulations.¹²

On July 7, 2010, the FDA solicited comments on how to implement the menu-labeling requirements.¹³ Although still receiving comments, the FDA published draft guidance to the industry in August 2010.¹⁴ In the draft guidance, the FDA interpreted the relevant portions of section 4205 to have gone into effect immediately upon enactment, but elected not to initiate any enforcement action until after a final rule had been promulgated.¹⁵ The draft guidance broadly interpreted “similar retail food establishments” to include entertainment venues like movie theaters, cafes and food courts in grocery stores, and “transportation carriers (*e.g.*, airlines and trains).”¹⁶ It did not mention schools or define “locations.”

The FDA withdrew the draft guidance on January 25, 2011,¹⁷ and issued its proposed menu-labeling rule for comments on April 6, 2011.¹⁸ The proposed rule identified the statutory term “similar retail food establishments” as ambiguous and proposed to define an establishment as similar to a restaurant (and therefore covered by the rule) “if it offers for sale restaurant or restaurant-type food and its primary

⁸ The nutrition-labeling provision was initially enacted as section 4205, Pub L. No. 111-148, § 4205, 124 Stat. 119, 573 (2010), and was codified at 21 U.S.C. § 343(q)(5).

⁹ 21 U.S.C. § 343(q)(5)(H)(i).

¹⁰ *Id.* § 343(q)(5)(H)(ii).

¹¹ *See id.*

¹² *See id.* § 343(q)(5)(H)(x).

¹³ *See* Disclosure of Nutrient Content Information for Standard Menu Items Offered for Sale at Chain Restaurants or Similar Retail Food Establishments and for Articles of Food Sold from Vending Machines, 75 Fed. Reg. 39,026 (July 7, 2010).

¹⁴ CTR. FOR FOOD SAFETY & APPLIED NUTRITION, *supra* note 7, at 1.

¹⁵ *Id.* at 13.

¹⁶ *Id.* at 6.

¹⁷ Draft Guidance for Industry: Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010; Withdrawal of Draft Guidance, 76 Fed. Reg. 4360 (Jan. 25, 2011).

¹⁸ Food Labeling; Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments, 76 Fed. Reg. 19,192 (proposed Apr. 6, 2011) [hereinafter Menu Labeling Proposed Rule] (to be codified at 21 C.F.R. pts. 11, 101).

business activity is the sale of food to consumers.”¹⁹ The proposed rule considered the sale of food to be an establishment’s “primary business activity” if the establishment either presented itself to the public as a restaurant or used greater than fifty percent of its gross floor area for the “preparation, purchase, service, consumption, or storage of food.”²⁰ Under the primary-business test, grocery stores that sold restaurant-type food would “generally” be covered by the rule, but movie theaters, trains, planes, schools, and hospitals would “generally” be exempted.²¹

On December 1, 2014, the FDA issued a final menu-labeling rule.²² Abandoning the primary-business test, the final rule applies to any establishment (including movie theaters) with 20 or more locations that “sell[s] restaurant-type food.”²³ The rule exempts schools from the definition of “similar retail food establishment.”²⁴ Where the statute applies to establishments with “20 or more locations,”²⁵ the final rule defines “location” as “a fixed position or site,” thus exempting trains, airplanes, and food trucks from the menu-labeling requirements.²⁶ Establishments must comply with the new rules by December 1, 2015.²⁷

While the menu-labeling rule’s expansive reach has drawn popular criticism,²⁸ the agency’s broad definition of “similar retail food establishment” is a permissible interpretation of the ACA, even though it in-

¹⁹ *Id.* at 19,196.

²⁰ *Id.* at 19,197. The FDA also sought comments on an alternative to the floor-area test that considered whether more than fifty percent of the establishment’s revenues are generated by food sales. *Id.*

²¹ *See id.* at 19,197 n.1, 19,198–99. Under certain proposed alternative primary-business tests (which relied on floor area used for the sale of restaurant-type food or percent of revenue generated by the sale of restaurant-type food), grocery stores would have generally *not* been covered. *Id.* at 19,198–99.

²² Menu Labeling Final Rule, *supra* note 4, at 71,156.

²³ *Id.* at 71,164–66.

²⁴ *Id.* at 71,169.

²⁵ 21 U.S.C. § 343(q)(5)(H)(i) (2012).

²⁶ Menu Labeling Final Rule, *supra* note 4, at 71,171 (internal quotation marks omitted). The rule requires that covered establishments declare the calorie content of standard menu items on menus, menu boards, and signs adjacent to self-service food (like buffets), *see id.* at 71,158, 71,176–82, 71,191–205, 71,218–29, that additional written nutrition information be made available upon request, *see id.* at 71,158, 71,212–18, and that menus and menu boards include a “succinct statement” explaining the suggested daily calorie intake for adults, *id.* at 71,158, 71,205–11, and notifying customers that the additional nutritional information is available, *see id.* at 71,158, 71,211–12. The rule specifies how establishments will determine, *see id.* at 71,158, 71,229–33, and substantiate, *see id.* at 71,158, 71,233–37, their food’s nutrition content and establishes terms and conditions under which establishments not covered by the rule could voluntarily opt in to its requirements, *see id.* at 71,158, 71,237–38.

²⁷ *Id.* at 71,240.

²⁸ *See, e.g.,* Sabrina Tavernise & Stephanie Strom, *F.D.A. to Require Calorie Count, Even for Popcorn at the Movies*, N.Y. TIMES (Nov. 24, 2014), <http://www.nytimes.com/2014/11/25/us/fda-to-announce-sweeping-calorie-rules-for-restaurants.html>.

cludes movie theaters and excludes schools. However, excluding airplanes, trains, and food trucks — under a definition of “location” that was introduced for the first time in the final rule — may be legally unsound as an impermissible interpretation and as a violation of notice-and-comment rulemaking procedures.

The FDA’s interpretations of the statutory terms “similar retail food establishment” and “location” are governed by the two-step analysis laid out in *Chevron U.S.A. Inc. v. Natural Resources Defense Council, Inc.*²⁹ First, a reviewing court determines whether a statutory term is ambiguous, and therefore open to agency interpretation, by looking to “whether Congress has directly spoken to the precise question at issue.”³⁰ “Similar retail food establishment” is ambiguous under *Chevron* step one. Congress did not define the term in the statute. In a comment, the National Association of Theatre Owners argued that the language of the ACA indicates that Congress “clearly” intended to reach only “chain retail food establishments,” which “no one would associate with movie theaters and other establishments where the sale of food is incidental to or quite separate from the establishment’s primary purpose.”³¹ However, Congress’s choice to include the phrase “or other similar retail food establishment” indicates an intention to reach more broadly than just “restaurants,” delegating to the FDA the task of defining criteria by which an establishment can be judged to be “similar” to a restaurant. The ACA’s language is in fact more vague than the legislation in California and New York City on which it was modeled. Those jurisdictions were more explicit about defining establishments that are covered (New York City) or exempted (California) under their calorie-labeling requirements.³²

If a court determines that “the statute is silent or ambiguous with respect to the specific issue,” it proceeds to *Chevron* step two and asks “whether the agency’s answer is based on a permissible construction of

²⁹ 467 U.S. 837 (1984).

³⁰ *Id.* at 842.

³¹ National Association of Theatre Owners, Comment on Menu Labeling Proposed Rule, at 2 (July 5, 2011). The only relevant legislative history the organization cites is language in a 2012 House Committee on Appropriations Report opposing a rule that “would include establishments that are not primarily in the business of selling food for immediate consumption.” *Id.* at 2 n.6 (quoting H.R. REP. NO. 112-101, at 53 (2012)). A committee report from a Congress that has changed leadership since the passage of the ACA shines little light on the intent of the Congress that passed the ACA. Even if the Committee’s report were authoritative, the report does not assert that “similar retail food establishments” clearly precludes including entertainment venues; it advocates that the “FDA should define the term ‘restaurant’ to mean only restaurants . . . where the primary business is the selling of food for immediate consumption.” *Id.* (emphasis added) (quoting H.R. REP. NO. 112-101, at 53) (internal quotation mark omitted).

³² See Act of Sept. 30, 2008, ch. 600, § 2(a)(1)(A)–(I), 2008 Cal. Stat. 4288, 4289, *repealed by* Act of Oct. 2, 2011, ch. 415, § 2, 2011 Cal. Stat. 4185, 4186; N.Y.C., N.Y., HEALTH CODE §§ 81.01, 81.50 (2015).

the statute.”³³ Here, the FDA has developed criteria to define “similar retail food establishment” that are permissible under *Chevron* step two. The FDA’s construction has precedent: the Nutrition Labeling and Education Act of 1990³⁴ (NLEA), in defining what establishments were exempt from nutrition-labeling requirements, had included among restaurants “other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments.”³⁵ The ACA explicitly amended the NLEA to remove this exemption. The menu-labeling rule defines “similar retail food establishments” to include establishments, like movie theaters, that are like restaurants in that they offer prepared food that is “ready for human consumption”³⁶ and eaten on the premises or very soon after leaving.³⁷ The menu-labeling rule thus covers establishments for the same reasons that they were included in the NLEA’s exemption.

Additionally, the FDA’s decision to exclude schools is permissible. The FDA responded to a comment advocating including “a school food service contractor that uses a central kitchen or cooks the same food for 20 schools” as a covered establishment under the rule.³⁸ Although the FDA’s previous regulations implementing the 1990 NLEA included schools in the category of restaurants and other similar establishments that were then *exempt* from labeling requirements, the FDA can also choose to treat schools separately from restaurants now that restaurants must label their menus.³⁹ In interpreting the ambiguous ACA term “similar retail food establishments” to exclude schools, the FDA found that “the traditional and long-standing role” of the Department of Agriculture (USDA) in regulating school meals was a sufficiently reasonable basis on which to decide to exclude food vendors in schools.⁴⁰ The determination is the same even though the ACA requires the FDA to promulgate regulations to define covered establishments.⁴¹ While in *Massachusetts v. EPA*⁴² the Court precluded an

³³ *Chevron*, 467 U.S. at 843.

³⁴ Pub. L. No. 101-535, 104 Stat. 2353 (codified as amended in scattered sections of 21 U.S.C.).

³⁵ See Menu Labeling Final Rule, *supra* note 4, at 71,165 (quoting 21 U.S.C. § 343(q)(5)(A)(i) (2006) (amended 2010)) (internal quotation mark omitted). In regulations, the FDA defined “other establishments” to include “e.g., institutional food service establishments, such as schools, hospitals, and cafeterias; transportation carriers, such as trains and airplanes; . . . [and] food service vendors, such as lunch wagons.” 21 C.F.R. § 101.9(j)(2)(ii) (2014).

³⁶ Menu Labeling Final Rule, *supra* note 4, at 71,165 (quoting 21 U.S.C. 343(q)(5)(A)(i) (2012)).

³⁷ See *id.*

³⁸ *Id.* at 71,169; see also Robert Wood Johnson Foundation Center to Prevent Childhood Obesity, Comment on Menu Labeling Proposed Rule, at 2 (July 5, 2011) (advocating including schools in menu-labeling requirements).

³⁹ Menu Labeling Final Rule, *supra* note 4, at 71,169.

⁴⁰ *Id.*

⁴¹ See 21 U.S.C. § 343(q)(5)(H)(x)(I).

⁴² 549 U.S. 497 (2007).

agency from relying on statutorily irrelevant factors — like the USDA’s authority over school meals — in refusing to exercise rule-making authority under an *unambiguous* statute,⁴³ the ambiguity of “similar retail food establishments” gives the FDA the authority to look to factors outside of the statute and decide to exclude schools from the menu-labeling rule.⁴⁴

The FDA’s decision to exclude airplanes, trains, and food trucks, however, is legally questionable. The final rule suggested for the first time that the statute’s application to establishments with “20 or more locations” is ambiguous and defines “location” as “a fixed position or site,”⁴⁵ thereby exempting airplanes, trains, and food trucks. The FDA introduced its definition of “location” in response to a comment asking for clarification about whether multiple locations of the same establishment in the same mall would count toward the “20 or more locations” that make a chain subject to the rule.⁴⁶ The definition is also in response to a comment seeking clarification that “mobile facilities (such as food trucks),” which were not mentioned in the proposed rule, would be covered if they had twenty or more locations.⁴⁷ With no legislative history relevant to the question of how to understand “location” in these examples, the FDA concluded that “location” required further definition, suggesting that it is an ambiguous statutory term under *Chevron* step one. The FDA consulted dictionaries to conclude that “the common meaning of the word ‘location’ involves a specific or fixed position *on land or portion of land*.”⁴⁸ Thus, the rule counts two storefronts in the same mall as two locations, but does not cover “food facilities that do not have a fixed position or site,” including trains, airplanes, and food trucks.⁴⁹

Even if uncertainty about how to count multiple storefronts within the same mall supports the FDA’s *Chevron* step one conclusion that

⁴³ *Id.* at 529, 533–34.

⁴⁴ *Cf.* *WildEarth Guardians v. U.S. EPA*, 751 F.3d 649 (D.C. Cir. 2014). In that case, the D.C. Circuit upheld the EPA’s decision not to include coal mines under its interpretation of the Clean Air Act, which requires the EPA to regulate a “stationary source[] . . . [that] causes, or contributes significantly to, air pollution which may reasonably be anticipated to endanger public health or welfare.” 42 U.S.C. § 7411(b)(1)(A) (2012). The EPA did not determine whether coal mines contribute to air pollution that endangers public health but denied the petition for rulemaking because it “must prioritize its actions in light of limited resources and ongoing budget uncertainties.” *WildEarth Guardians*, 751 F.3d at 651 (quoting Notice of Final Action on Petition from Earthjustice to List Coal Mines as a Source Category and to Regulate Air Emissions from Coal Mines, 78 Fed. Reg. 26,739 (May 8, 2013) (to be codified at 40 C.F.R. pt. 63)) (internal quotation mark omitted).

⁴⁵ Menu Labeling Final Rule, *supra* note 4, at 71,171.

⁴⁶ *Id.*

⁴⁷ *Id.*

⁴⁸ *Id.* (emphasis added).

⁴⁹ *Id.*

“location” is ambiguous, the FDA’s construction to exclude mobile sites is likely impermissible under *Chevron* step two. When a court evaluates the reasonableness of an agency’s interpretation under *Chevron* step two, it examines the interpretation’s “fit” with the statutory language as well as its conformity to statutory purposes.”⁵⁰ While “location” may be ambiguous at the margins where two stores are operating on opposite ends of a mall, the FDA’s construction of “location” as tied to a tract of land is inconsistent with the statutory purpose of section 4205 of the ACA, which is to define a unit by which to count the number of franchises in a chain. Although airplanes, trains, and food trucks *move* their locations, they have unique, countable locations at any given moment in time.⁵¹ The result of the FDA’s construction is that a chain that operates nineteen storefronts and one food truck, or serves food on hundreds of airplanes, would not be covered by the rule, but a chain that operates twenty storefronts in the same mall would be. This construction focuses on a statutorily irrelevant factor — whether a location can move — to undermine the statute’s purpose, which is to provide consumers with nutrition information when they order restaurant-type food.

Not only is the FDA’s definition of “location” vulnerable under *Chevron*, but it is also procedurally vulnerable. The Administrative Procedure Act (APA), which governs notice-and-comment rulemaking,⁵² requires that the final rule an agency adopts be the “logical outgrowth” of the rule proposed.⁵³ The logical outgrowth requirement is an interpretation of the APA requirement that agencies provide in a notice of proposed rulemaking “either the terms or substance of the proposed rule or a description of the subjects and issues involved.”⁵⁴ This requirement serves the principle of providing “fair notice.”⁵⁵

⁵⁰ *Abbott Labs. v. Young*, 920 F.2d 984, 988 (D.C. Cir. 1990); see also *Goldstein v. SEC*, 451 F.3d 873, 881–84 (D.C. Cir. 2006) (finding SEC’s designation of investors in a hedge fund as “clients” of that fund inconsistent with the relevant statute’s text and purpose).

⁵¹ Although an agency often wins a case at *Chevron* step two, see Jason J. Czarnecki, *An Empirical Investigation of Judicial Decisionmaking, Statutory Interpretation, and the Chevron Doctrine in Environmental Law*, 79 U. COLO. L. REV. 767, 775 (2008), some scholars have argued that the two steps of *Chevron* are in fact two ways of articulating the same inquiry, see, e.g., Matthew C. Stephenson & Adrian Vermeule, Essay, *Chevron Has Only One Step*, 95 VA. L. REV. 597 (2009). Thus, it is possible to articulate the legal issue with the FDA’s construction of “location” as a *Chevron* step one problem: the statutory context in which “location” appears — as a unit by which to count the number of franchises in a chain — unambiguously prohibits the FDA from defining “location” as necessarily connected to a “tract of land”; the mobility or immobility of a location is irrelevant to the purpose of the statute in which “location” appears.

⁵² 5 U.S.C. § 553(b)–(c) (2012).

⁵³ *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007) (quoting *Nat’l Black Media Coal. v. FCC*, 791 F.2d 1016, 1022 (2d Cir. 1986)) (internal quotation marks omitted).

⁵⁴ 5 U.S.C. § 553(b)(3).

⁵⁵ *Long Island Care*, 551 U.S. at 174; see also *AFL-CIO v. Donovan*, 757 F.2d 330, 338–40 (D.C. Cir. 1985) (invalidating for failure to provide adequate notice a final rule that introduced for

Public comments are likely insufficient to provide fair notice,⁵⁶ especially here, where the two comments about “location” raised questions for clarification and did not propose definitions of “location.”⁵⁷ The FDA’s decision to define “location” for the first time in a final rule fails the logical outgrowth test. Neither the draft guidance nor the proposed rule mentioned food trucks specifically, and the public could not have been on notice that the agency would treat food trucks separately from restaurants (under the primary-business test, food trucks would presumably be covered). Similarly, while the public was on general notice that whether airplanes and trains would be included within the definition of “similar retail food establishment” was at least up for debate, the public had no fair notice of, and thus no meaningful opportunity to comment on, the wisdom of using the definition of “location” to exclude those businesses. By contrast, the public had fair notice that the agency was considering whether “similar retail food establishments” should include movie theaters and exclude schools because both of those establishments were discussed in the proposed definition of “similar retail food establishment.”⁵⁸ The public was therefore on notice that movie theaters could be included or excluded from the definition of “similar retail food establishment,” and their inclusion is a “logical outgrowth” of the proposed rule.

A large buttered popcorn can pack up to 1,200 calories,⁵⁹ which is 60% of the total daily suggested calorie intake for an adult.⁶⁰ The FDA acted legally in bringing this information to consumers at the concession stand — and in choosing to leave school meals to the USDA. But for vendors in airplanes, trains, and food trucks, the FDA should open up its definition of “location” to public comment to vet the legality and wisdom of failing to disclose nutrition information to their customers.

the first time a “substantial performance” test for whether a contract was performed in the United States); *Chocolate Mfrs. Ass’n of U.S. v. Block*, 755 F.2d 1098, 1105–07 (4th Cir. 1985) (invalidating for failing to provide adequate notice a final rule banning flavored milk from the Women, Infants, and Children (WIC) program even though the proposed rule indicated that the agency was looking to limit the “sugar, fat, and salt” content of permitted foods, *id.* at 1106).

⁵⁶ *Chocolate Mfrs.*, 755 F.2d at 1103 (finding a lack of fair notice notwithstanding the fact that the agency explained its rule through reference to seventy-eight comments (out of over 1,000) that called for banning flavored milk from the WIC program).

⁵⁷ See Menu Labeling Final Rule, *supra* note 4, at 71,171.

⁵⁸ Menu Labeling Proposed Rule, *supra* note 18, at 19,197–98, 19,197 n.1.

⁵⁹ Jayne Hurley & Bonnie Liebman, *BIG: Movie Theaters Fill Buckets . . . and Bellies*, CENTER FOR SCI. PUB. INT. (Dec. 2009), <http://www.cspinet.org/nah/articles/moviepopcorn.html> [http://perma.cc/GKR7-2JQ2].

⁶⁰ The menu-labeling rule requires restaurants to post the following succinct statement: “2,000 calories a day is used for general nutrition advice, but calorie needs vary.” Menu Labeling Final Rule, *supra* note 4, at 71,256.