FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

KYM PARDINI; CARRIE WOOD, on behalf of themselves and all others similarly situated, *Plaintiffs-Appellants,* v. UNILEVER UNITED STATES, INC., a Delaware corporation, *Defendant-Appellee.*	No. 21-16806 D.C. No. 4:13-cv-01675-JSW OPINION

Appeal from the United States District Court
for the Northern District of California
Jeffrey S. White, District Judge, Presiding

Argued and Submitted December 5, 2022
San Francisco, California

Filed April 18, 2023

Before: Carlos F. Lucero,[*] Daniel A. Bress, and Lawrence VanDyke, Circuit Judges.

[*] The Honorable Carlos F. Lucero, United States Circuit Judge for the U.S. Court of Appeals for the Tenth Circuit, sitting by designation.

Opinion by Judge Bress;
Dissent by Judge Lucero

SUMMARY**

Food Drug and Cosmetic Act / Preemption

The panel affirmed the district court's Fed. R. Civ. P. 12(b)(6) dismissal, based on express preemption by the federal Food Drug and Cosmetic Act (FDCA), of the plaintiffs' claims challenging the product label on "I Can't Believe It's Not Butter! Spray."

The Butter! Spray is a butter-flavored vegetable oil dispensed in pump-action squirt bottles with a spray mechanism. The front label on the product states that the Butter! Spray has 0 calories and 0 grams of fat per serving. Plaintiffs are a class of consumers who brought their lawsuit against the then-manufacturer, Unilever United States, Inc., contending that the product's label makes misrepresentations about fat and calorie content based on artificially low serving sizes.

The district court found that plaintiffs failed to plausibly allege that Butter! Spray was not a "spray type" fat or oil under Food and Drug Administration (FDA) regulations. The district court further held that the FDCA preempted plaintiffs' serving size claims. Because the

** This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

nutrient content claims were predicated on the serving size claims, those claims also failed on preemption grounds.

The FDCA's preemption provision can preempt state law statutory and common law causes of action to the extent those claims would directly or indirectly impose nutrition label requirements different than those prescribed by federal law. The FDA has devised elaborate rules for appropriate food serving sizes. Under the specific regulations governing butter and related products, the Butter! Spray falls into two possible subcategories: "spray types" and "butter, margarine, oil, shortening."

The panel held that, as a matter of legal classification, Butter! Spray was a "spray." In common parlance, a "spray" refers to liquid dispensed in the form of droplets, emitted from a mechanism that allows the product to be applied in that manner. In addition, the notion that Butter! Spray could be housed under the FDA's legal classification for "butter" is implausible. Plaintiffs agreed that to generate one tablespoon of "butter," 40 sprays of Butter! Spray would be required. Common sense shows that this is not how such a product is typically used. The panel also rejected plaintiffs' argument that Butter! Spray is a "butter substitute" based on how it is marketed, so that it should be treated as "butter" for serving size purposes, too. Because Unilever properly characterized Butter! Spray as a "spray type" fat or oil, the serving size on its nutrition label complied with federal law.

Finally, the panel considered plaintiffs' argument that consumers do not typically use just one spray of Butter! Spray, and that Unilever's serving size information was therefore misleading because serving sizes must reflect customary usage. The panel held that plaintiffs' theory had it backwards. It is the FDA that sets the reference amounts

for serving sizes, and to comply with federal law, manufacturers then identify the relevant product category and set a serving size that approximates the FDA's reference amount for that category. In alleging that consumers use more than one spray of Butter! Spray, plaintiffs do not raise a question of fact regarding product classification, but instead challenge the reference amount customarily consumed—a value established by the FDA. The proper forum in which to air such a grievance is the FDA (or Congress), not the courts. Because plaintiffs' challenge to the Butter! Spray serving sizes would "directly or indirectly establish" a requirement for food labeling that is "not identical" to federal requirements, 21 U.S.C. § 343-1(a)(4), the FDCA preempts their serving size claims. It therefore follows that plaintiffs' claims about fat and calorie content are preempted as well.

Dissenting, Judge Lucero wrote that the majority erred in its Fed. R. Civ. P. 12(b)(6) review by conflating the plausibility of plaintiffs' claims with the preemption evaluation. The result is that Unilever's burden to establish preemption is inappropriately lessened. In order to establish preemption as an affirmative defense, Unilever must prove that Butter! Spray is properly categorized as a "spray type" rather than a "butter, margarine, oil, [or] shortening." He would hold that Unilever has not carried its burden of proving that Butter! Spray must be categorized as "spray type," and would reverse the 12(b)(6) dismissal and remand for continued proceedings.

COUNSEL

Ureka E. Idstrom (argued), The Eureka Law Firm, Kansas City, Missouri; Justin T. Berger and Sarvenaz J. Fahimi, Cotchett Pitre & McCarthy LLP, Burlingame, California; for Plaintiffs-Appellants.

James R. Sigel (argued) and Claudia M. Vetesi, Morrison & Foerster LLP, San Francisco, California; Adam L. Sorensen, Morrison & Foerster LLP, Washington, D.C.; Megan Whipp, The Law Office of Megan L. Whipp PC, Beverly Hills, California; for Defendant-Appellee.

OPINION

BRESS, Circuit Judge:

Over 125 years ago, the Supreme Court decided whether a tomato is a fruit or a vegetable. *See Nix v. Hedden*, 149 U.S. 304, 307 (1893) (the answer: a vegetable). In a more modern iteration of this legal genre, we today decide, in effect, whether the product "I Can't Believe It's Not Butter! Spray" is a butter or a spray. The question turns out to matter because the plaintiff consumers contend that the product's label makes misrepresentations about fat and calorie content based on artificially low serving sizes.

We hold that the information on the product's label complies with federal food labeling requirements for "spray type" fats and oils. The product is a spray under federal regulations, and it was labeled accordingly. We affirm the district court's dismissal of plaintiffs' claims because the federal Food Drug and Cosmetic Act (FDCA) expressly preempts them.

I

We recite the facts as alleged in plaintiffs' complaint. This is a consumer class action challenging the labels on I Can't Believe It's Not Butter! Spray. To avoid a lengthy acronym, we will refer to this product as "Butter! Spray." "Butter! Spray" is part of the "I Can't Believe It's Not Butter!" product line, consisting of margarine foods and vegetable oil spreads that are marketed as healthier alternatives to butter. The implication of the well-known brand name is, of course, that the product tastes so much like butter that one could not believe it wasn't.

Launched in 1994, Butter! Spray is a "butter-flavored vegetable oil" dispensed in "pump-action squirt bottles" with a "spray mechanism." Plaintiffs allege it is "used by consumers interchangeably with butter." The front label on the product states that Butter! Spray has 0 calories and 0 grams of fat per serving. The front label also proclaims that the product is "Great for Topping & Cooking." It depicts an ear of corn, suggesting that Butter! Spray may be used as a flavoring for corn on the cob.

On the nutrition panel, which appears on the back of the bottle, the label lists serving sizes for two different applications: "cooking spray" and "topping." For each application, the nutrition panel provides the serving size by weight and in terms of the number of "sprays." For the "cooking spray" application, the serving size is "1 Spray (0.20g)." When used as a "topping," the serving size is stated as "5 Sprays (1g)." For both applications, the nutrition panel indicates that a serving size has 0 calories and 0 grams of fat.

This lawsuit, brought against then-manufacturer Unilever, alleges that Butter! Spray's nutrient content claims

are misleading because they are based on unrepresentative serving sizes. As we discuss below, when a product's FDA-designated serving size contains amounts of calories and fat that are below certain thresholds, federal regulations allow (and in some instances require) the product to be labeled as having zero calories or fat per serving. Plaintiffs allege that an entire 12-ounce bottle of Butter! Spray contains 1160 calories and 124 grams of fat. Plaintiffs claim that because the serving sizes on Butter! Spray are "artificially small," Butter! Spray is not, in fact, "0 fat" or "0 calories" per serving.

In plaintiffs' view, the serving sizes on the Butter! Spray nutritional panel are too low to "reflect customary usage." "Because consumers use [Butter! Spray] to achieve a comparable buttery flavor," plaintiffs also allege that under the FDCA and its implementing regulations, Butter! Spray "belongs in the same product category as butter itself with a required serving size of one tablespoon," rather than as a "spray type" fat or oil. The amount of fat and calories that would be present in a tablespoon of Butter! Spray could not be represented as "zero" under FDCA regulations. Plaintiffs allege that consumers have expressed confusion and frustration upon learning that larger servings of the product contain non-negligible amounts of calories and fat. Had they known "the true nature" of Butter! Spray, plaintiffs would not have purchased the product or would have paid less for it.

Advancing state law causes of action, plaintiffs sought to certify a nationwide class of consumers who had purchased Butter! Spray. After several rounds of proceedings, the district court, under Rule 12(b)(6), dismissed with prejudice plaintiffs' claims based on serving size and nutrient content. The court found that plaintiffs failed to plausibly allege that

Butter! Spray was not a "spray type" fat or oil under FDA regulations. The FDCA thus preempted plaintiffs' serving size claims. And because the nutrient content claims were predicated on the serving size claims, those claims also failed on preemption grounds. Proceedings on other claims not at issue here ended in the denial of class certification and summary judgment against the plaintiffs.

Plaintiffs appeal the dismissal of only their serving size and nutrient content claims, which the district court found preempted. We review the grant of a Rule 12(b)(6) motion de novo, construing the allegations of the complaint in plaintiffs' favor. *Nguyen v. Endologix, Inc.*, 962 F.3d 405, 413 (9th Cir. 2020). A "complaint may be dismissed when the allegations of the complaint give rise to an affirmative defense that clearly appears on the face of the pleading." *Boquist v. Courtney*, 32 F.4th 764, 774 (9th Cir. 2022). Preemption, on which the defendant bears the burden, *Cohen v. ConAgra Brands, Inc.*, 16 F.4th 1283, 1289 (9th Cir. 2021), can be such a defense. *See, e.g.*, *Durnford v. MusclePharm Corp.*, 907 F.3d 595, 602 (9th Cir. 2018).

II

A

Plaintiffs' lawsuit implicates a vast federal regime governing food labeling. To understand why plaintiffs' claims are preempted, it is necessary to describe this scheme in some detail.

The FDCA creates rules for the labeling of food products. 21 U.S.C. § 301 *et seq.* This includes nutritional information. *Id.* § 343(q). As a general matter, foods that are intended for human consumption and offered for sale must contain labeling that provides "the serving size[,]

which is an amount customarily consumed and which is expressed in a common household measure that is appropriate to the food." *Id.* § 343(q)(1)(A)(i). The label must also depict, among other things, the number of calories and the amount of fat "in each serving size or other measure of the food." *Id.* § 343(q)(1)(C), (D).

As amended by the Nutrition Labeling and Education Act, the FDCA generally guarantees uniform food labeling nationwide by expressly prohibiting states from "directly or indirectly" establishing "any requirement for [the] nutrition labeling of food that is not identical" to federal requirements. 21 U.S.C. § 343-1(a)(4); *see also Lilly v. ConAgra Foods, Inc.*, 743 F.3d 662, 664–65 (9th Cir. 2014). The U.S. Food and Drug Administration (FDA) has interpreted the FDCA to prohibit "any statute, standard, regulation, or other requirement . . . issued by a State" that "directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food" additional to or different from "those specifically imposed by or contained in the applicable provision (including any implementing regulation)" of the FDCA. 21 C.F.R. § 100.1(b)(5), (c)(4)(ii). It is well established that the FDCA's preemption provision can preempt state law statutory and common law causes of action, like the ones plaintiffs assert here, to the extent those claims would directly or indirectly impose nutrition label requirements different than those prescribed by federal law. *See, e.g.*, *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008).

The FDA has implemented the FDCA's nutrition labeling requirements in voluminous regulations. These regulations provide that "all nutrient and food component quantities shall be declared in relation to a serving as defined in" the regulations. 21 C.F.R. § 101.9(b). The regulations

further require that food labels contain nutrition panels listing certain information for each serving size, such as calorie content and fat. *Id.* § 101.9(c). Particularly relevant here, if a product has less than 5 calories per serving, the calorie content per serving "may be expressed as zero." *Id.* § 101.9(c)(1). If a product has less than 0.5 grams of fat per serving, the fat content on the nutrition panel "shall be expressed as zero." *Id.* § 101.9(c)(2). Similar rules govern nutrient content information provided elsewhere on the product (like the front of the Butter! Spray bottle). *See id.* §§ 101.60(b)(1)(i), 101.62(b)(1)(i). These regulations explain the apparent prevalence of products that contain nonnegligible amounts of calories and fat based on the total amount in the food container as sold, but that are nonetheless (lawfully) labeled and advertised as containing no calories or fat per serving.[1]

Of course, the larger the serving of a food product, the more calories and fat are ingested. The FDA has thus devised elaborate rules for appropriate food serving sizes, rules which are central to this case. Under FDA regulations, "[t]he term serving or serving size means an amount of food customarily consumed per eating occasion by persons 4 years of age or older which is expressed in a common household measure that is appropriate to the food." *Id.* § 101.9(b)(1). These regulations are highly detailed in

[1] If a product states that it contains zero fat because it falls below 0.5 grams / serving but the product also contains fat as an ingredient or "is generally understood by consumers to contain fat," the product label must include "an asterisk that refers to the statement below the list of ingredients, which states 'adds a trivial amount of fat,' 'adds a negligible amount of fat,' or 'adds a dietarily insignificant amount of fat.'" 21 C.F.R. § 101.62(b)(1)(i)–(ii). The plaintiffs in this case also brought an "asterisk claim," but that claim is not before us.

nature. *See, e.g.*, *id.* § 101.9(b)(2)(i)(E) ("The serving size for maraschino cherries shall be expressed as 1 cherry with the parenthetical metric measure equal to the average weight of a medium size cherry."). We will thus describe the serving size rules only as relevant to this case.

Serving size—the "amount of food customarily consumed per eating occasion"—is set by the FDA "based on data set forth in appropriate national food consumption surveys." *Id.* § 101.12(a)(1) & Table 2 n.1. Under the regulations, "[a]n appropriate national food consumption survey includes a large sample size representative of the demographic and socioeconomic characteristics of the relevant population group and must be based on consumption data under actual conditions of use." *Id.* § 101.12(a)(3). The FDA bases serving size reference amounts on "the major intended use of a food," for example, "milk as a beverage and not as an addition to cereal." *Id.* § 101.12(a)(7). The FDA's ultimate aim is "to ensure that foods that have similar dietary usage, product characteristics, and customarily consumed amounts have a uniform reference amount." *Id.* § 101.12(a)(9). Thus, although people vary in their eating habits, the FDA has determined that serving sizes should be standardized based on broader, data-driven generalizations about how foods are customarily consumed during an eating occasion.

The FDA's prescribed serving size amounts for the general food supply are set forth in a lengthy "Table 2" appearing at 21 C.F.R. § 101.12(b). Serving sizes "shall be determined from" this table, *id.* § 101.9(b)(2), which is entitled "Reference Amounts Customarily Consumed Per Eating Occasion: General Food Supply," *id.* § 101.12(b), Table 2. The table organizes seemingly everything humans eat into various product categories and subcategories. For

example, under the first category, "Bakery Products," we find items ranging from croissants and pineapple upside-down cake to melba toast and taco shells. *Id.* § 101.12(b), Table 2. Under "Desserts," we encounter guilty pleasures such as sundaes and custards. *Id.* And so on.

The FDA's table contains three columns. The first is the product category. *Id.* The second is the FDA's "reference amount," which is, again, the "amounts customarily consumed per eating occasion." *Id.* § 101.12(a). This is typically expressed in grams, milliliters, or other similar measurements. For instance, we are told that the reference amount for a serving of croutons is 7 grams. *Id.* § 101.12(b), Table 2. For smoked or pickled fish, it is 55 grams. *Id.* For pickles themselves, 30 grams. *Id.*

The third column in the FDA's table is entitled "Label statement." "The label statements are meant to provide examples of serving size statements that may be used on the label, but the specific wording may be changed as appropriate for individual products." *Id.* § 101.12(b), Table 2 n.4. Thus, to return to croissants, the example label statement reads: "__ piece(s) (__g)." *Id.* The FDA instructs that "[m]anufacturers are required to convert the reference amount to the label serving size in a household measure most appropriate to their specific product using" other prescribed procedures. *Id.* n.3. "[C]ommon household measure[s]" include units such as cups, tablespoons, pieces, and so on. *Id.* § 101.9(b)(5).

Some items are known as "nondiscrete bulk products." *Id.* § 101.9(b)(2)(iii). These items are not customarily eaten in discrete units. The regulations give as examples consumables such as breakfast cereals, flour, and pancake mixes. *Id.* For these kinds of products, the serving size

"shall be the amount in household measure that most closely approximates the reference amount for the product category" in the reference table. *Id.*

We now turn to the more specific regulations governing butter and related products. Table 2 in § 101.12(b) contains a product category entitled "Fats and Oils," and within it several subcategories. We provide this portion of the table here, which reflects the three columns (product category, reference amount, and label statement):

Fats and Oils:		
Butter, margarine, oil, shortening	1 tbsp	1 tbsp (_ g); 1 tbsp (15 mL)
Butter replacement, Powder	2 g	_ tsp(s) (_ g)
Dressings for salads	30 g	_ tbsp (_ g); _ tbsp (_ mL)
Mayonnaise, sandwich spreads, mayonnaise-type dressings	15 g	_ tbsp (_ g)
Spray types	0.25 g	About __ seconds spray (_ g)

Id.

Butter! Spray does not fall within most of the subcategories in "Fats and Oils." It is not a powder or a salad dressing, nor is it akin to a mayonnaise or sandwich spread. But two subcategories are possibilities: "spray types" and

"butter, margarine, oil, shortening." If the latter legal classification applies, the serving size on the Butter! Spray nutritional panel was incorrect, as were the fat and calorie representations. But isn't Butter! Spray not *real* butter, the reader may ask? It turns out that the FDA's regulations further provide that "the reference amount for an imitation or substitute food or altered food, such as a 'low calorie' version, shall be the same as for the food for which it is offered as a substitute." *Id.* § 101.12(d). To decide the preemption question, we thus must resolve, based on the allegations in the complaint, whether, as a matter of law, I Can't Believe It's Not Butter! Spray should be classified as a butter/oil or a spray.

B

As a matter of legal classification, it is a spray. Although plaintiffs claim there are factual disputes at play here, in truth plaintiffs simply disagree with the FDA's framework for how these types of products should be labeled. These arguments may be readily addressed—and readily rejected—at the Rule 12(b)(6) stage.

We interpret regulations, like statutes, based on their plain language. *Wards Cove Packing Corp. v. Nat'l Marine Fisheries Serv.*, 307 F.3d 1214, 1219 (9th Cir. 2002). In common parlance, a "spray" in this context refers to liquid dispensed in the form of droplets, emitted from a mechanism that allows the product to be applied in that manner. There is no well-pleaded allegation in the complaint that, in form and function, Butter! Spray is anything other than a spray. Images in the complaint and record indicate that the product comes in a spray bottle, with a finger-activated pump at the top. Plaintiffs at one point in their operative complaint themselves reference the product's "spray mechanism."

They similarly describe the product as one that is "dispensed in pump-action squirt bottles." These allegations support Unilever's characterization of Butter! Spray as a spray, based on the properties of the product and the liquified form in which it is indisputably applied.

The notion that Butter! Spray could be housed under the FDA's legal classification for "butter," meanwhile, is simply implausible. The FDA's "reference amount" for "butter, margarine, oil, [and] shortening" is 1 tablespoon. 21 C.F.R. § 101.12(b), Table 2. Plaintiffs agree that to generate one tablespoon of Butter! Spray, *40 sprays* would be required. "[C]ommon sense," *Ashcroft v. Iqbal*, 556 U.S. 662, 679 (2009), tells us that this is not how such a product is typically used. Nor does the plaintiffs' complaint allege otherwise. The complaint states at one point that some consumers "report using far more than one spray" and that "[s]ome even admit to pouring the product." But under the FDCA and its implementing regulations, serving sizes are based on amounts "customarily consumed." 21 U.S.C. § 343(q)(1)(A)(i); 21 C.F.R. §§ 101.9(b)(1), 101.12(a). There is no well-pleaded allegation in the complaint that consumers customarily drown their food in 40 sprays of I Can't Believe It's Not Butter! Spray.

And even if this were somehow plausible, the category of "spray type" would still be the more proper legal classification when construing the "Fats and Oils" category as a whole. *See Norfolk Energy, Inc. v. Hodel*, 898 F.2d 1435, 1442 (9th Cir. 1990) ("In discerning the meaning of regulatory language, our task is to interpret the regulation as a whole, in light of the overall statutory and regulatory scheme, and not to give force to one phrase in isolation." (citation and quotation marks omitted)). Plaintiffs argue that Butter! Spray is a "butter substitute" based on how it is

marketed, so that it should be treated as "butter" for serving size purposes, too. But under the FDA regulations, a "substitute" food is not merely one that tastes the same (believably or not). It is instead defined as a food that "may be used interchangeably with another food that it resembles, i.e., that is organoleptically, physically, and functionally (including shelf life) similar to, and that it is not nutritionally inferior to unless it is labeled as an 'imitation.'" 21 C.F.R. § 101.13(d).

Plaintiffs have not pleaded facts that would fully satisfy this technical definition for a product "substitute." But even if they could get over that hurdle, and even if we were to make the implausible assumption that consumers customarily use 40 sprays of the product per eating occasion, it would still be more appropriate to place Butter! Spray in the FDA's "spray type" category under the familiar principle that the specific governs the general. *See, e.g.*, *Flores v. Barr*, 934 F.3d 910, 917 (9th Cir. 2019) (citing *Karczewski v. DCH Mission Valley LLC*, 862 F.3d 1006, 1015–16 (9th Cir. 2017)). "Spray type" quite plainly encompasses a narrower category than "butter, margarine, oil, [and] shortening," with "spray type" referring to fats and oils that may be dispensed in a liquid emulsion using a spray mechanism. Most any oil can fit in the "butter, margarine, oil, shortening" category, but not every butter or oil-based product can be sprayed. Treating Butter! Spray as a butter/oil rather than a spray would threaten to undermine the specific categorization in the FDA's regulatory scheme, potentially rendering the "spray type" category meaningless. Nor do we agree with plaintiffs that "spray type" should be limited to aerosolized sprays (like "Pam") or nonstick

cooking sprays. Neither the FDA regulations nor agency guidance impose these limitations.[2]

Because Unilever properly categorized Butter! Spray as a "spray type" fat or oil, the serving size on its nutrition label complied with federal law. For the "cooking spray" application, the Butter! Spray label lists the serving size as "1 Spray (0.20g)." A "spray" is a "common household measure that is appropriate to the food." 21 C.F.R. § 101.9(b)(1). The FDA's suggested "label statement" for a spray is expressed in "seconds" of spray, but the regulations are clear that the "label statements are meant to provide examples" which can be revised "as appropriate for individual products." *Id.* § 101.12(b), Table 2 n.4. Thus, contrary to the dissent's assertions, nothing required Unilever to express usage based on "seconds" of spray. For "spray types," the FDA reference table provides a mandatory reference amount of 0.25 grams. *Id.* § 101.12(b), Table 2.

[2] Our fine dissenting colleague would reach a different result in this case on the theory that the "spray types" category includes only nonstick cooking sprays. But the dissent purports to base this position on the FDA's "agency guidance," when the agency has made no such proclamation. The 1994 FDA document on which the dissent relies does not state that "spray types" *only consist* of nonstick cooking sprays. And regardless, the FDA in 2018 updated its guidance on spray types, now describing as "examples" of this product "*[a]ll types* of cooking sprays (e.g., cooking spray olive oil)." *See* FDA, Guidance for Industry: Reference Amounts Customarily Consumed for Each Product Category (2018) (emphasis added). That inclusive guidance undermines the dissent's attempt to narrow the "spray types" category to aerosolized nonstick sprays like Pam. Contrary to the dissent's assertions, the 2018 FDA guidance poses no retroactivity problem. There has been no relevant change to the statute or regulations, and the 2018 guidance merely makes clearer what the 1994 guidance already conveyed: that "spray types" are not limited to nonstick cooking sprays.

But because Butter! Spray is a "nondiscrete bulk product," its serving size "shall be the amount in household measure that most closely approximates the reference amount for the product category" in the reference table. *Id.* § 101.9(b)(iii); *see also id.* § 101.12(b), Table 2 n.3. Unilever's 0.2-gram figure "closely approximates" the FDA's reference amount. Plaintiffs do not state a claim by pointing to the very small difference between the spray weight on the product label and the value provided in the FDA reference table.

The Butter! Spray label also lists as an alternative serving size "5 Sprays (1g)" when the product is used as "topping" (toppings can be sprayed). Unilever was not required to include this alternative serving size because "nondiscrete bulk products" are exempt from FDA regulations requiring additional nutritional information for alternative uses. *Id.* § 101.9(b)(11). But Unilever was not prohibited from including this information, and plaintiffs do not state a claim simply because Unilever voluntarily provided it. Plaintiffs' assertion that the "5 spray" portion of the nutritional label is unauthorized is incorrect.

C

Trying a different approach, plaintiffs argue that consumers do not typically use just one spray of Butter! Spray, and that Unilever's serving size information is therefore misleading because "serving sizes must reflect customary usage." In plaintiffs' view, food manufacturers must determine how their customers consume food products, creating a supposed issue of fact both in this case and presumably every other lawsuit like this alleging that customers eat more of something than an FDA serving size would suggest.

Plaintiffs' theory has it backwards. It is the FDA that sets the reference amounts for serving sizes based on the data "set forth in appropriate national food consumption surveys." 21 C.F.R. § 101.12(a)(1). To comply with federal law, manufacturers then identify the relevant product category and set a serving size that approximates the FDA's reference amount for that category. *Id.* §§ 101.9(b)(2), 101.12(b). In a lawsuit such as this, whether the serving size listed on the nutritional label is lawful is not a factual question about consumer behavior, but rather a legal question that turns on whether the manufacturer identified the proper product category and complied with the applicable product category regulations.

In alleging that consumers use more than one spray of Butter! Spray, plaintiffs do not raise a question of fact regarding product classification. They instead challenge the reference amount customarily consumed—a value established by the FDA. As the district court correctly recognized, plaintiffs' approach would allow consumers to "overcome a motion to dismiss" by "insisting that people consume more (or less) of a product" than the FDA reference amount, "rendering all sorts of products mislabeled at a consumer's whim." That is not the law. In view of the FDCA's express preemption provision, if plaintiffs believe that Butter! Spray should have a higher customary usage reference amount, the proper forum in which to air that grievance is the FDA (or Congress), not the courts.

Contrary to plaintiffs' suggestion, our decision in *Lilly v. ConAgra Foods, Inc.*, 743 F.3d 662 (9th Cir. 2014), provides plaintiffs no support. There, we considered whether the FDCA preempted state law claims alleging that ConAgra misled consumers about the sodium content of its sunflower seeds. *Id.* at 663–64. Under the FDCA and its implementing

regulations, a food label must include the sodium content of the "edible portion" of the food, but it need not include the sodium content of a "seed, shell, or other inedible component." *Id.* at 665 (citing 21 C.F.R. §§ 101.9(b)(9), 101.12(a)(6)). It was "indisputabl[e]" in *Lilly* that the salted coating is consumed when a sunflower seed is eaten. *Id.* The question was then whether "the sodium content of the edible coating added to sunflower seeds must, under federal law, be included in the nutritional information disclosed" on the product package. *Id.* at 663.

The issue was ultimately a legal one: whether the coating was an "edible portion" within the meaning of certain FDA regulations. *Id.* at 665. We held that it was, which meant that plaintiffs' state law claims were not seeking to impose different requirements than federal law and were thus not preempted. *Id.* To the extent *Lilly* drew on how customers consumed the product, that the seed coating was intended to be ingested was, again, "indisputabl[e]." *Id.* *Lilly* had nothing to do with the FDA's serving size rules, and it did not somehow direct that customer usage should be evaluated in answering the preemption question in a case such as this. In assessing preemption under the FDCA for claims challenging the serving size on a food product, we do not work backward from customer usage to a product category (the FDA's role), but rather forward from a product category to the serving size FDA has assigned that category.

Plaintiffs do not dispute that, if Butter! Spray is properly labeled as a "spray type" fat or oil with a serving size approximating 0.25 grams (here 0.2 grams), Butter! Spray's calorie and fat content representations also comply with federal law. As we discussed above, for nutrition labels the FDA regulations allow products with fewer than 5 calories per serving to be labeled as having zero calories, while

products with less than 0.5 grams of fat per serving size are required to be labeled as having zero fat. *See* 21 C.F.R. §§ 101.9(c)(1)–(2); *see also id.* §§ 101.60(b)(1)(i), 101.62(b)(1)(i) (similar rules for other product labels). It is undisputed that the fat and calorie amounts for a 1-spray serving of Butter! Spray fall below these thresholds (as does a 5-spray serving). Thus, Butter! Spray nutrient labels that the dissent calls "deception" fully comply with federal law.

Because plaintiffs' challenge to the Butter! Spray serving sizes would "directly or indirectly establish" a requirement for food labeling that is "not identical" to federal requirements, 21 U.S.C. § 343-1(a)(4), the FDCA preempts their serving size claims. It follows that plaintiffs' claims about fat and calorie content are preempted as well. Once again, if plaintiffs (or the dissent) believe that the FDA should not allow products to be labeled as containing zero fat or calories when a given serving size may contain some of each, they may raise that issue with the agency. This argument cannot overcome the FDCA's express preemption provision.

AFFIRMED.

LUCERO, Circuit Judge, dissenting:

The proposition that, absent some Canaan miracle, a bottle of flavored oil containing 1,160 calories and 124 grams of fat can be transformed into zero calories and zero grams of fat by the simple act of replacing the bottle cap with a pump device is ludicrous. Yet, that is appellee Unilever's defense to appellants' state law consumer protection claims. Unilever answers the appellants' claims not by asserting some molecular change that would result in such a

transformation, but by asserting that the claims are preempted by the FDCA. In other words, appellee tells us that its labelling complies with FDA requirements, allowing it to label its product as containing zero calories and zero grams of fat. Because I disagree with my respected colleagues in their analysis that permits Unilever to engage in such deception, I must dissent.

As a preliminary matter, the majority errs in its 12(b)(6) review by conflating the plausibility of appellants' claims, as required by Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009), with the preemption evaluation, required by Reid v. Johnson & Johnson, 780 F.3d 952, 959-61 (9th Cir. 2015). The two evaluations are separate and distinct. See, e.g., Ebner v. Fresh, 838 F.3d 958, 964-67 (9th Cir. 2016); Reid, 780 F.3d at 958-59; Williams v. Gerber Products Co., 552 F.3d 934, 937-41 (9th Cir. 2008); Painter v. Blue Diamond Growers, 757 F. App'x 517, 518-20 (9th Cir. 2018). What results from my respected colleagues' merger of the assessments, is that Unilever's burden to establish preemption is inappropriately lessened.

In order to establish preemption as an affirmative defense, Unilever must prove, under the Act, the regulations, and Reid, 780 F.3d at 959-61, that its labelling is authorized. This means it must prove that *I Can't Believe It's Not Butter Spray* is properly categorized as a "spray type" rather than a "butter, margarine, oil, [or] shortening." In establishing preemption, I wholeheartedly agree that we begin with the plain text of the statute. See Jones v. Rath Packing Co., 430 U.S. 519, 525 (1977). This ensures state police powers are "not to be superseded . . . unless that was the clear and manifest purpose of Congress." Rice v. Santa Fe Elevator Corp., 331 U.S. 218, 230 (1947). If there are "plausible alternative reading[s]" of express language, we "have a duty

to accept the reading that disfavors pre-emption." Bates v. Dow Agrosciences LLC, 544 U.S. 431, 449 (2005).

I do not agree that in the context of the statutory text and regulations, the term "spray" is clear. Appellants' complaint avers that the product at issue "is sold to consumers in a plastic bottle fitted with a removeable pump-action squirt nozzle" that "delivers discrete squirts with each push—not a pressurized aerosol spray like Pam that is dispensed by pressing down for a period of time." Accepting that allegation for 12(b)(6) purposes, I am not ready to declare as a legal proposition that a "squirt" is a "spray."

When plain text does not provide clarity, we may consider agency guidance interpretating the regulations. Skidmore v. Swift Co., 323 U.S. 134, 140 (1944). Compellingly, FDA guidelines provide that "spray types" include exclusively "nonstick cooking sprays (e.g., Pam)." U.S. Food and Drug Admin., Inspections, Compliance, Enforcement, & Criminal Investigations, Guide to Nutrition Labeling & Educ. Act Regs. (Attach. 26)(1994).[1] This is

[1] My distinguished colleagues correctly identify a 2018 update to this guidance document. However, the operative complaint was filed in 2013 and in 2014 the district court granted a motion to dismiss on the issue before us. As the Supreme Court has succinctly stated:

> [T]he presumption against retroactive legislation is deeply rooted in our jurisprudence, and embodies a legal doctrine centuries older than our Republic. Elementary considerations of fairness dictate that individuals should have an opportunity to know what the law is and to conform their conduct accordingly; settled expectations should not be lightly disrupted. For that reason, the "principle that the legal effect of conduct should ordinarily be assessed under the law

consistent with the overall FDA regulations that provide for "spray types" to be measured in seconds, indicating a

> that existed when the conduct took place has timeless and universal appeal." Kaiser, 494 U.S., at 855, 110 S. Ct., at 1586 (Scalia, J., concurring). In a free, dynamic society, creativity in both commercial and artistic endeavors is fostered by a rule of law that gives people confidence about the legal consequences of their actions.

Landgraf v. USI Film Prods., 511 U.S. 244, 265-66 (1994).

The Ninth Circuit regularly applies the applicable law at the time of filing. See, e.g., Woods v. Kijakazi, 32 F.4th 785, 789-90 (9th Cir. 2022); Friends of Animals v. U.S. Fish & Wildlife Serv., 28 F.4th 19, 24 n.1 (9th Cir. 2022); Whitewater Draw Nat. Res. Conservation Dist. v. Mayorkas, 5 F.4th 997, 1004 n.1 (9th Cir. 2021); United States v. Patton, 771 F.2d 1240, 1242 n.1 (9th Cir. 1985). Applying this principle to guidance, this Circuit has noted that finding otherwise would harm plaintiffs bringing suits. Indep. Training and Apprenticeship Program v. Cal. Dept. of Indus. Relations, 730 F.3d 1024, 1034-35 (9th Cir. 2013) (declining to automatically defer to DOL opinion letters issued after litigation commenced). Unilever can hardly argue otherwise as it could also claim lack of fair notice if the situation was reversed. Indeed, the Ninth Circuit has recognized the Due Process concerns of holding a defendant to requirements published after the claim was filed. United States v. AMC Entm't, Inc., 549 F.3d 760, 768-70 (9th Cir. 2008).

In any event, appellee Unilever does not present any arguments regarding the 2018 guidance. In fact, Unilever addressed the 1994 guidance document briefed by appellants but did not reference the 2018 guidance document in its briefing. It is not our role to guess what argument Unilever could have made regarding the 2018 guidance. And, again, this case comes before us on Rule 12(b)(6) review and it is not our office to enter findings of fact that are contrary to the allegations of the complaint. On Rule 12(b)(6) review, "we treat the complaint's allegations as true and construe them in the light most favorable to the plaintiff[s]." Nguyen v. Endologix, Inc., 962 F.3d 405, 408 (9th Cir. 2020).

continuous mist. 21 C.F.R. § 101.12(b). It is also consistent with *I Can't Believe It's Not Butter* online recipes, which indicate that their product should be used with "no-stick skillet(s)," clearly implying it is not intended as a "nonstick cooking spray."

Inclusion of butter substitutes in the "spray type" category frustrates regulatory purpose. FDA labelling guidelines are designed to protect consumers from "false or misleading" packaging. 21 U.S.C. § 343(a) (2012). As my majoritarian colleagues state, the categories are meant to reflect "the major intended use of the food (e.g., milk as a beverage and not as an addition to cereal)." 21 C.F.R. § 101.12(a)(7):

- The "spray type" category has a major intended use: "nonstick cooking sprays" that lubricate pans with continuous sprays measured in seconds.
- The general "butter, margarine, oil, [and] shortening" category, measured by the tablespoon, encompasses products used as an ingredient or topping.

Our role is to determine if Unilever has proven *I Can't Believe It's Not Butter Spray* must be categorized as "spray type." In my opinion, Unilever has not carried that burden.

In context of the clear language of the statute and regulations, at trial the fact finder could properly find that *I Can't Believe It's Not Butter Spray* is categorized in the "butter, margarine, oil, [and] shortening" category rather than as a "spray." Such a finding would well square with the reality that even though squirted from a bottle, the product contains the expected calories rather than zero calories. I

would reverse the 12(b)(6) dismissal by the district court and remand the case for continued proceedings.