FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

ELENA NACARINO; MEGAN TAYLOR, *Plaintiffs-Appellants*, v. KASHI COMPANY, *Defendant-Appellee*.	No. 22-15377 D.C. No. 3:21-cv-07036-VC OPINION

MOLLY BROWN; ADINA RINGLER; CHRISTIAN LEMUS, *Plaintiffs-Appellants*, v. KELLOGG COMPANY, *Defendant-Appellee*.	No. 22-15658 D.C. No. 3:21-cv-07388-VC

Appeal from the United States District Court
for the Northern District of California
Vince Chhabria, District Judge, Presiding

Argued and Submitted May 10, 2023
San Francisco, California

Filed August 14, 2023

Before: Sidney R. Thomas, Morgan Christen, and Daniel A. Bress, Circuit Judges.

Opinion by Judge Christen

SUMMARY*

Federal Preemption / Product Labeling

The panel affirmed on different grounds the district court's dismissal of two complaints alleging that food product labels advertising the amount of protein in the products were false and misleading under both federal and state law.

The federal Food, Drug, and Cosmetic Act expressly preempts all state statutes and law that establish requirements for the labeling of food that are not identical to the federal requirements set forth by statute and Food and Drug Administration ("FDA") regulations. Under FDA regulations, even if protein quantity is calculated using a federally approved method, promoting a protein's quantity outside of the label's Nutritional Facts Panel could be misleading if the product contains lower-quality protein and

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

the Nutritional Facts Panel does not disclose the percent daily value of the protein adjusted for the protein's quality.

The panel rejected Plaintiffs' arguments that the protein claims on Defendants' labels were false because the nitrogen method for calculating protein content overstated the actual amount of protein the products contained. The panel held that FDA regulations specifically allow manufacturers to measure protein quantity using the nitrogen method, to display that value in the Nutritional Facts Panel, and to use it to make a quantitative nutrient content claim.

The panel rejected Plaintiffs' arguments that the protein claims on Defendants' labels were misleading because the "amount of digestible or usable protein the Products actually deliver to the human body is even lower" than the actual amount of protein the products contain. The panel held that Defendants' protein claims could be misleading under FDA regulations if they did not accurately state the quantity of protein or if the products did not display the quality-adjusted percent daily value in the Nutritional Facts Panel. However, Plaintiffs' complaints did not allege that the challenged protein claims were misleading within the meaning of the federal regulations.

The panel held that, to the extent that state law would hold Defendants to a different standard, Plaintiffs' state-law claims were expressly preempted.

Finally, the panel held that the FDA regulations are not ambiguous and are sufficient to support the preemption holding, but the agency's interpretations of its own regulations reinforce that conclusion.

COUNSEL

Matthew T. McCrary (argued), Gutride Safier LLP, Boulder, Colorado; Seth A. Safier, Gutride Safier LLP, San Francisco, California; for Plaintiffs-Appellants.

Andrianna Kastanek (argued) and Dean N. Panos, Jenner & Block LLP, Chicago, Illinois; Alexander M. Smith, Jenner & Block LLP, Los Angeles, California; for Defendants-Appellees.

OPINION

CHRISTEN, Circuit Judge:

In these consolidated appeals, we must decide whether food product labels that advertise the amount of protein in the products are false or misleading. Plaintiffs allege that the products' front labels are false and misleading because they overstate the products' protein quantity and implicitly exaggerate protein quality. The district court disagreed. It reasoned that the protein claims on Defendants' front labels could not be false or misleading under federal law because Defendants measured protein quantity using a method approved by the Food and Drug Administration. Because any state labeling requirements that differ from federal requirements are preempted, and the court concluded that Defendants' labels comply with federal law, the court dismissed Plaintiffs' complaints.

We agree with the district court's analysis of the preemption principles that apply to these appeals, and with the court's ultimate conclusion that Plaintiffs' claims are

preempted. But we read the federal food labeling regulations differently. Even if protein quantity is calculated using a federally approved method, promoting a product's protein quantity outside of the label's Nutrition Facts Panel could be misleading if the panel does not disclose the percent daily value of protein adjusted for the protein's *quality*. Here, we nevertheless affirm the district court's dismissal of Plaintiffs' complaints because neither of them alleges that the Nutrition Facts Panels on Defendants' product labels omitted the required protein quality-adjusted percent daily value information.

I

Two putative class actions are at issue in these appeals: *Nacarino v. Kashi Co.*, No. 22-15377, and *Brown v. Kellogg Co.*, No. 22-15658. The complaints were filed in the Northern District of California, and they asserted materially identical state-law consumer protection claims for unfair business practices, unjust enrichment, and fraud. Both complaints alleged that the front labels on several of Defendants' products are "false and misleading" under state and federal law. In Plaintiffs' view, the front labels of Defendants' products "broadly tout protein quantity while ignoring . . . the poor quality proteins in their products." Plaintiffs argue that Defendants' protein claims are false and misleading because the human body cannot absorb and use all the protein in foods that contain low-quality protein.

We review de novo an order granting a motion to dismiss for failure to state a claim, and construe a complaint's allegations in favor of the plaintiff. *Bolden-Hardge v. Off. of Cal. State Controller*, 63 F.4th 1215, 1220 (9th Cir. 2023). A district court may dismiss a complaint when its allegations "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, can be such a defense." *Pardini v. Unilever U.S., Inc.*, 65 F.4th 1081, 1084 (9th Cir. 2023) (internal citation omitted).

The Food, Drug, and Cosmetic Act (FDCA),[1] as amended by the Nutrition Labeling and Education Act (NLEA),[2] expressly preempts all state statutes and law that "directly or indirectly establish any requirement for the labeling of food that is not identical to the federal requirements" set forth by statute and Food and Drug Administration (FDA) regulations. *Hawkins v. Kroger Co.*, 906 F.3d 763, 769 (9th Cir. 2018) (internal quotation marks omitted) (quoting *Reid v. Johnson & Johnson*, 780 F.3d 952, 959 (9th Cir. 2015)).[3] The FDCA express-preemption provision relevant here is 21 U.S.C. § 343-1(a)(5). "The preemption analysis turns on whether the challenged statements are authorized by the FDA's regulations or other pronouncements of similar legal effect." *Reid*, 780 F.3d at 959. The parties dispute whether the state-law requirements that Plaintiffs invoke differ from the requirements imposed by the FDCA and its implementing regulations. As we explain, we conclude that federal law authorizes Defendants' quantitative protein claims, and that Plaintiffs' state-law claims seek to impose different requirements from those

[1] Pub. L. No. 75-717, 52 Stat. 1040 (1938).

[2] Pub. L. No. 101-535, 104 Stat. 2353 (1990).

[3] *See* 21 U.S.C. § 343-1(a)(5); *see also id.* § 343(q)(1)(D), (r)(1)(A), (r)(2)(A)(i); 21 C.F.R. § 100.1(b)(5), (c)(4)(ii).

prescribed by federal law. As such, Plaintiffs' state-law claims are preempted. [4]

II

A

Understanding Plaintiffs' claims requires some background on the nature of protein and federal nutrition-labeling regulations. The complaints allege that protein, composed of amino acid chains, varies in quality based on its digestibility and the balance of the amino acids it contains. Different protein sources supply different amounts of amino acids. Some amino acids are considered essential because the human body cannot make them on its own. This means that two food products containing the same amount of protein by weight may differ in two important respects: how much of the food's protein can be absorbed and used by the human body, and how well the food's protein will fulfill a person's nutritional needs.

The FDCA, enacted in 1938, establishes that a food is misbranded if its labeling is "false or misleading in any particular."[5] In 1990, Congress amended the FDCA through

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[4] Plaintiffs also argue that the district court erred by failing to acknowledge or apply the presumption against preemption. But "[w]hen, as here, 'the statute contains an express pre-emption clause, we do not invoke any presumption against pre-emption but instead focus on the plain wording of the clause, which necessarily contains the best evidence of Congress' pre-emptive intent.'" *Int'l Bhd. of Teamsters, Loc. 2785 v. Fed. Motor Carrier Safety Admin.*, 986 F.3d 841, 853 (9th Cir. 2021) (quoting *Puerto Rico v. Franklin Cal. Tax-Free Tr.*, 579 U.S. 115, 125 (2016)). Regardless, the result in this case would be the same even if there were a presumption against preemption that needed to be overcome.

[5] 21 U.S.C. § 343(a).

the NLEA and mandated nutrition labeling—and the now-ubiquitous Nutrition Facts Panels (NFPs)—on many products.[6] The NLEA and its implementing regulations require manufacturers to include on food labels NFPs that disclose the number of calories and the amount of fat, carbohydrates, and protein in their products.[7] NFPs are usually printed on the side or back of a product's packaging.[8] The statute and regulations, including 21 C.F.R. § 101.13, specify what claims manufacturers may make about a food's nutrient content on product labels *outside* of the NFP, such as on the front label.[9] When manufacturers make a claim outside the NFP that describes the amount of one of the nutrients required to be included in the NFP, FDA regulations refer to the statement as a "nutrient content claim," or, if the statement describes protein, a "protein claim."[10] The challenged claims here are protein claims because they appear outside the NFP and characterize the amount of protein in the products. For example, the front label on a box of Kashi Go Cinnamon Crisp cereal includes an "11g Protein" claim, and the front label on Kellogg's Special K cereal includes a "PROTEIN 15g" claim.

There are different regulations for front labels and NFPs, but the front-label regulations explicitly refer to, and incorporate, some standards from the NFP regulations. Relevant here, section 101.13(i)(3) authorizes manufacturers to make nutrient content claims about the "amount or

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[6] *Id.* § 343(q); *see Hawkins*, 906 F.3d at 769; *Reid*, 780 F.3d at 959.

[7] 21 U.S.C. § 343(q)(1)(C)–(D); 21 C.F.R. § 101.9(c).

[8] *See* 21 C.F.R. §§ 101.2, 101.9(i), (j)(13), (j)(17).

[9] 21 U.S.C. § 343(r)(1)(A); 21 C.F.R. § 101.13(b); *see id.* § 101.2(a).

[10] 21 C.F.R. § 101.13(b); *see id.* § 101.9(c)(7)(i).

percentage of a nutrient" outside the NFP if the claim "does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect."[11]

Section 101.13 does not include a specific rule for measuring protein for purposes of nutrient content claims. Rather, section 101.13(o) provides that "compliance with [the] requirements for nutrient content claims . . . will be determined using the analytical methodology prescribed for determining compliance with nutritional labeling in § 101.9," an NFP regulation.[12] The pertinent part of that regulation, section 101.9(c)(7), requires that manufacturers include protein quantity in the NFP measured by "the number of grams of protein in a serving," and allows protein quantity to be calculated based on the food's nitrogen content.[13] This measure of protein quantity can be "corrected" to more accurately reflect the food's nutritive value by multiplying the measured protein content by the "protein digestibility-corrected amino acid score"

[11] *Id.* § 101.13(i)(3). This provision includes two examples of permissible nutrient content claims: "100 calories" and "5 grams of fat." *Id.* Plaintiffs do not dispute that, like these examples, the challenged nutrient content claims do not implicitly characterize the level of a nutrient in Defendants' products. The quantitative protein claims at issue here are a type of "expressed nutrient content claim," a term that the regulations define as "any direct statement about the level (or range) of a nutrient in the food." *Id.* § 101.13(b)(1).

[12] *Id.* § 101.13(o).

[13] *Id.* § 101.9(c)(7).

(PDCAAS), a measure of protein quality.[14] High-quality proteins, such as whey, have a PDCAAS of 1, and lower-quality proteins, including many plant-based proteins, have a PDCAAS of less than 1. Critical for purposes of these appeals, if a label includes a protein claim (by definition, a claim outside the NFP), it triggers a provision in section 101.9(c)(7)(i) that requires the manufacturer to display PDCAAS-corrected protein content as a percent daily value figure within the NFP in addition to displaying protein quantity in grams.[15] We refer to this provision as the "trigger provision."

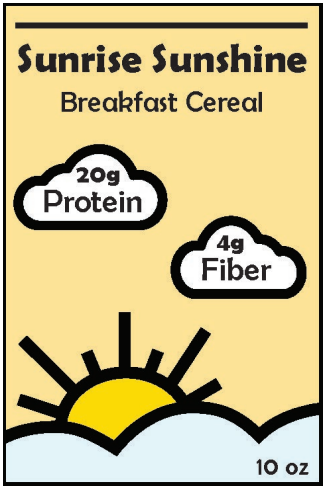
The following exemplar product label illustrates how these interlocking regulations work.[16] The "20g Protein" nutrient content claim on the front of the exemplar label matches the protein quantity displayed in the NFP. The percent daily value figures for adults are calculated using a reference value of 50 grams.[17] Because the percent daily value figure shown in the exemplar NFP (30%) is less than the gram value of the protein content divided by 50 grams (20g ÷ 50g = 40%), the NFP indicates a lower-quality protein with a PDCAAS of less than 1.

[14] *Id.* The regulations specify how to calculate protein content using the nitrogen method and how to adjust that value using PDCAAS. *See id.* § 101.9(c)(7) & (7)(ii).

[15] *Id.* § 101.9(c)(7)(i).

[16] We include these illustrations solely to show how the regulations for nutrient content claims interact with the regulations for NFPs.

[17] *See* 21 C.F.R. § 101.9(c)(7)(iii).



Nutrition Facts

About 6 servings per container

Serving size	**1 Cup (45g)**
Amount Per Serving	
Calories	**180**
	% Daily Value*
Total Fat 5g	**6%**
Saturated Fat 0g	**0%**
Trans Fat 0g	
Cholesterol 0mg	**0%**
Sodium 270mg	**12%**
Total Carbohydrate 14g	**5%**
Dietary Fiber 4g	**16%**
Total Sugars 7g	
Includes 6g Added Sugars	**12%**
Protein 20g	**30%**

Not a significant source of vitamin D, calcium, iron, and potassium

*The % Daily Value (DV) tells you how much a nutrient in a serving of food contributes to a daily diet. 2,000 calories a day is used for general nutrition advice.

B

Plaintiffs argue that Defendants' protein claims are both false and misleading—violating state and federal law—because the labels overstate the products' protein content and imply that all of the protein contained in the products is usable by the human body. In its motion to dismiss the *Nacarino* complaint, Kashi argued that Plaintiffs' state-law claims were preempted because the FDA regulations authorize quantitative protein claims outside the NFP and the challenged protein claims are fully compliant with the federal regulations. Kashi also argued that explicit "FDA guidance" from an FDA webpage contradicts Plaintiffs' argument that federal law requires Kashi to remove the protein claims from its product labels.

The district court granted Kashi's motion and dismissed the complaint with prejudice. *See Nacarino v. Kashi Co.*, 584 F. Supp. 3d 806, 807 (N.D. Cal. 2022). The court concluded that accepting Plaintiffs' theory would require it "to find that an FDA-approved protein measurement

technique is inherently misleading," an interpretation it deemed implausible. *Id.* at 810. The district court also dismissed *Brown*, finding the claims alleged there indistinguishable from those alleged in *Nacarino*.[18]

Two months before oral argument in our court, the district court issued a ruling in a similar case, *Rausch v. Flatout, Inc*., No. 22-cv-04157-VC, ___ F. Supp. 3d ____, 2023 WL 2401452 (N.D. Cal. Mar. 8, 2023). The *Rausch* defendant advertised protein content on its front labels without including the quality-adjusted percent daily value figure in the NFP. *Id.* at *2. The district court denied a motion to dismiss the *Rausch* complaint. *Id*. at *6. In doing so, the court retreated from the statement in its order granting the motion to dismiss the *Nacarino* complaint—that an "FDA-approved protein measurement technique" *could not be* misleading within the meaning of the FDA regulations—and instead held that "prominently advertising a product's protein quantity outside of the nutrition facts panel *is* misleading (within the meaning of the [FDCA] and the FDA's regulations), if the manufacturer doesn't include the quality-adjusted percent in the nutrition facts panel." *Id.* at *5. Before hearing oral argument, we requested supplemental briefing to address the district court's ruling in *Rausch*. Now, having considered the parties' briefing, we clarify that a protein claim *could be* misleading within the meaning of the applicable food labeling regulations if the NFP does not disclose the product's protein quality *and* the product contains lower-quality protein.

[18] No party has argued on appeal that *Nacarino* and *Brown* are distinguishable.

III

We interpret a regulation based on its plain language and in the context of the regulatory scheme, and defer to an agency's interpretation of its own regulation only when it is "genuinely ambiguous." *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019); *see Christensen v. Harris County*, 529 U.S. 576, 588 (2000). Plaintiffs' complaints allege that the challenged protein claims are: (1) false because the nitrogen method overstates the actual amount of protein the products contain; and (2) misleading because the "amount of digestible or usable protein the Products actually deliver to the human body is even lower" than the actual amount of protein the products contain.[19] We address these arguments in turn.

A

The text and structure of the federal regulations preclude Plaintiffs' argument that Defendants' protein claims are false. "False" means "[c]ontrary to fact or truth."[20] Plaintiffs focus narrowly on the text of two parts of the

[19] FDA regulations do not specify a standard for "false or misleading," but the agency has issued guidance stating that it employs a "reasonable consumer" standard. *See* 67 Fed. Reg. 78002-01, 78003 (Dec. 20, 2002); *id.* at 70004 (rejecting the Ninth Circuit's earlier interpretation of the FDCA as protecting "'the ignorant, the unthinking, and the credulous' consumer" (quoting *United States v. El-O-Pathic Pharmacy*, 192 F.2d 62, 75 (9th Cir. 1951)). After the FDA issued this guidance, we have applied the reasonable consumer standard to FDCA preemption claims. *See, e.g.*, *Hawkins*, 906 F.3d at 771 (citing *Reid*, 708 F.3d at 962–63).

[20] *False*, Am. Heritage Dictionary (5th ed. 2022), https://ahdictionary.com/word/search.html?q=false [https://perma.cc/9L5D-UKQM].

regulation addressing nutrient content claims.[21] This overlooks that interlocking regulatory provisions for nutrient content claims and NFPs work together to create an integrated regulatory scheme, and that examining the scheme as a whole reveals a more complete story. Section 101.13(o) provides that compliance with the requirements for nutrient content claims, such as the quantitative protein claims challenged here, is determined using section 101.9's "analytical methodology." And section 101.9(c)(7) authorizes the use of the nitrogen method to measure protein quantity. *See Durnford v. MusclePharm Corp.*, 907 F.3d 595, 603 (9th Cir. 2018) (noting that 21 C.F.R. § 101.9(c)(7) "allow[s] nitrogen to be used on the [NFP] as a proxy for protein content"). In other words, section 101.13(o) expressly allows Defendants to make a nutrient content claim based on the nitrogen method, as they have done here.

Plaintiffs do not dispute that Defendants used the nitrogen method to measure the amount of protein in their quantitative protein claims. Instead, they argue that Defendants' protein claims are false because Defendants could have measured protein content more accurately by directly measuring the products' amino acid content.[22] Our decision in *Durnford* cuts against Plaintiffs' argument.

In *Durnford*, the plaintiff alleged that defendant MusclePharm spiked its product with nitrogenous

[21] *See* 21 C.F.R. § 101.13(c) & (i)(3).

[22] Measuring a product's amino acid content is a separate step that is required to calculate the PDCAAS for that product. *See Rep. of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation*, U.N. Doc. E/1/12.91/2300, at 35 (1989), https://perma.cc/CK4M-NH5K; 21 C.F.R § 101.9(c)(7)(ii) (incorporating by reference the "Report of the Joint FAO/WHO Expert Consultation on Protein Quality Evaluation.").

compounds to falsely inflate its protein content. *Id.* at 601. We held that the plaintiff's state-law claim based on the protein quantity listed in the NFP was expressly preempted by 21 C.F.R. § 101.9(c)(7) because that regulation "allow[s] the use of nitrogen content as a proxy for protein" and the label's NFP reflected the product's nitrogen content. *Id.* at 602. We observed that the FDCA's prohibition on "false or misleading statements *in general*" did not alter the analysis because the plaintiff did not argue that section 101.9(c)(7)'s designation of the nitrogen method for measuring protein quantity "exceeded [the agency's] congressionally delegated authority." *Id.* (first citing *Chevron, U.S.A., Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843 (1984); and then citing *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001)).

Plaintiffs here make an argument similar to the one *Durnford* rejected—that a protein quantity calculated using the authorized nitrogen method is false because it overstates what Plaintiffs consider to be the true amount of protein. This argument fails because the regulations specifically allow manufacturers to measure protein quantity using the nitrogen method, to display that value in the NFP, and to use it to make a quantitative nutrient content claim.

Plaintiffs argue that allowing section 101.9(c)(7)'s NFP rules to determine whether a protein claim is "false or misleading" would render 101.13(c) superfluous. We are not persuaded. Section 101.13(c) provides that when information required or permitted in the NFP—such as protein quantity—is displayed outside the NFP, it becomes subject to section 101.13's requirements for nutrient content claims.[23] We agree with Plaintiffs that, on its own, the requirement that a statement be made in the NFP "does not

[23] 21 C.F.R. § 101.13(c).

give the manufacturer license to make the same claim elsewhere on the product." *Hawkins*, 906 F.3d at 771; *see Reid*, 780 F.3d at 963. But in the case of quantitative protein claims (e.g., "11g Protein"), section 101.13 provides that such claims may be based on the nitrogen method prescribed by section 101.9(c)(7) to calculate protein content. The key provision is section 101.13(o), which directs that compliance with requirements for nutrient content claims will be determined using the "analytical methodology" for NFPs in section 101.9(c)(7).[24] Section 101.9(c)(7) includes the nitrogen method. Read together, sections 101.13(o) and 101.9(c)(7) permit manufacturers to make protein claims that state protein quantity measured using the nitrogen method. This does not render 101.13(c) superfluous; our decisions in *Reid* and *Hawkins* illustrate that section 101.13(c) still has independent effect in instances when the agency has authorized statements to appear in the NFP but has declined to authorize those statements elsewhere on the package.

In *Hawkins*, the plaintiff challenged a nutrient content claim that a product contained "0g Trans Fat per serving." 906 F.3d at 767. In fact, the product did contain trans fat, and Hawkins brought state-law claims similar to those in *Nacarino* and *Brown*. *Id.* At the relevant time, the pertinent provision of section 101.9 included a rounding rule for disclosing fat content for various types of fat, including trans fat: "[I]f the serving contains less than 0.5 gram, the content shall be expressed [in the NFP] as zero." *Id.* at 770 (quoting 21 C.F.R. § 101.9(c)(2)(ii) (2015)).

In considering whether this provision preempted Hawkins's claims, we observed that, under section

[24] *See id.* § 101.13(c) & (o); *see also id.* § 101.9(c)(7)(i)–(iii).

101.13(c), "a statement as to the amount of a nutrient mandated inside the Nutrition Facts Panel is not necessarily permitted by the FDCA elsewhere on the packaging." *Id.* The *Hawkins* court was not writing on a blank slate: *Reid* had already held that a product label that contained the statement "No Trans Fat" was false where a product actually contained some trans fat. *Id.* (citing *Reid*, 780 F.3d at 963). *Reid* and *Hawkins* rested on the observation that a different rule that specifically addressed nutrient content claims about fat content

> *expressly allowed* "No Fat" and "No Saturated Fat" nutrient content claims for products that contain less than 0.5 grams of fat or saturated fat per serving. By contrast, the FDA explicitly decided *not* to authorize a "No Trans Fat" nutrient content claim in light of a lack of scientific information.

Id. at 771 (emphasis added) (quoting *Reid*, 780 F.3d at 962). *Reid* explained:

> If section 101.13(i)(3) authorizes "No Fat" and "No Saturated Fat" claims for products with small amounts of fat or saturated fat, then why would the FDA go to the trouble of promulgating a separate regulation expressly allowing these claims? It would be incongruous to have the same rule for both "No Fat"/"No Saturated Fat" and "No Trans Fat" claims, as the former is expressly permitted while the latter is not due to a lack of scientific consensus about the dangers of trans fat. Thus, the FDA's reading of section 101.13(i)(3)—that the

> regulation does not authorize "No Trans Fat" claims—makes the most sense of the overall labeling regime . . . .

780 F.3d at 963.

Here, there is no comparable separate regulation or other indicia that the FDA specifically allowed some protein claims, but not quantitative protein claims. Contrary to Plaintiffs' argument that the regulations do not authorize quantitative protein claims based on the nitrogen method, the interlocking provisions of the FDA's regulatory scheme provide that: (1) the nitrogen method may be used to calculate protein quantity in the NFP and to make quantitative protein claims, *see* 21 C.F.R. §§ 101.9(c)(7), 101.13(o); and (2) if a product label includes a protein claim *outside* the NFP, section 101.9(c)(7)(i)'s trigger provision requires the manufacturer to also include the PDCAAS-corrected percent daily value *inside* the NFP, *id.* § 101.9(c)(7)(i) ("A statement of the corrected amount of protein per serving . . . *may* be placed on the [NFP], except that such a statement *shall* be given if a protein claim is made for the product . . . ." (emphases added)). Reading section 101.13(o) alongside section 101.9(c)(7)(i) demonstrates that food manufacturers are authorized to make protein claims based on the nitrogen method, so long as they also include the quality-adjusted protein content as a percent daily value in the NFP. *See United States v. Grandberry*, 730 F.3d 968, 981–82 (9th Cir. 2013) ("[A] statute or regulation should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous, void or insignificant." (alteration accepted) (quoting *Corley v. United States*, 556 U.S. 303, 314 (2009)).

Reading section 101.13(i)(3) to authorize quantitative protein claims based on the nitrogen method, so long as the NFP also displays a PDCAAS-corrected percent daily value figure, reconciles the overall labeling regime and gives meaning to all the relevant regulatory provisions, including the trigger provision. Plaintiffs' complaints do not allege that Defendants' protein claims fail to accurately represent nitrogen-measured protein content or that Defendants' NFPs omitted the percent daily value figures required by the trigger provision. Accordingly, the complaints do not allege that the challenged protein claims are "false" within the meaning of section 101.13(i)(3).

B

Plaintiffs separately contend that the challenged protein claims are misleading because they imply that consumers will "receive all the nutritional and dietary benefits" of the specified quantity of protein. "Mislead" means "[t]o give a wrong impression or lead toward a wrong conclusion, especially by intentionally deceiving."[25] Plaintiffs argue that protein claims like "11g Protein" and "PROTEIN 15g" on Defendants' labels are misleading, even if they are technically accurate as to the amount of protein, because they inflate the nutritive value of low-quality protein.

Plaintiffs point to our decision in *Williams v. Gerber Products Co.*, 552 F.3d 934 (9th Cir. 2008), and a more recent Seventh Circuit opinion that relied on *Gerber*—*Bell v. Publix Super Markets, Inc.*, 982 F.3d 468 (7th Cir. 2020)—to argue two points. First, Plaintiffs contend that

[25] *Mislead*, Am. Heritage Dictionary (5th ed. 2022) https://ahdictionary.com/word/search.html?q=mislead [https://perma.cc/BF5C-358T].

manufacturers cannot "mislead consumers [on the front label] and then rely on the [NFP] to correct those misinterpretations and provide a shield for liability for the deception." *Gerber*, 552 F.3d at 939. Second, Plaintiffs posit that "average consumers are not likely to be aware of the nuances of the FDA's regulations" pertaining to how the percent daily value requirements in the NFP account for protein quality. *Bell*, 982 F.3d at 482.

Neither of these cases assist Plaintiffs' cause. *Gerber* is inapt because it did not address federal law. The front label at issue in *Gerber* juxtaposed the words "Fruit Juice" with images of "oranges, peaches, strawberries, and cherries." 552 F.3d at 936. The plaintiffs alleged that the front label was deceptive because "the only juice contained in the product was white grape juice from concentrate." *Id.* Our court agreed, but we did so under California law and explicitly declined to consider whether the FDCA preempted the plaintiffs' claims because the defendants failed to raise preemption in the district court, forfeiting the issue. *Id.* at 937. *Gerber* thus suggests the claims presented in the *Nacarino* and *Brown* complaints could be cognizable under state law, but the case provides no guidance as to whether they are preempted.

The Seventh Circuit's *Bell* decision is more instructive because that court considered FDCA preemption and concluded that those plaintiffs' claims could proceed. The challenged front labels in *Bell* stated that defendants' products contained "100% Grated Parmesan Cheese." 982 F.3d at 473. The plaintiffs alleged that the products actually contained "between four and nine percent added cellulose powder and potassium sorbate," and that this was indicated only in fine print on a back-label ingredients list. *Id.* The *Bell* defendants argued that the FDCA expressly preempted

the plaintiffs' state-law claims because FDA regulations authorized (and required) defendants to market the products as "Grated Parmesan Cheese." *Id.* at 483–86 (quoting 21 C.F.R. § 133.146(c) & (d)(3)(i)).[26] The Seventh Circuit rejected defendants' express preemption argument because the applicable federal regulations were silent on the modifier "100%." *Id.* at 483–84. Accordingly, a false-or-misleading state-law claim about "*100%* Grated Parmesan Cheese" was not expressly preempted, even though a claim about "Grated Parmesan Cheese" would have been preempted. Applying this logic here, a false-or-misleading state-law claim about something like "11g High-Quality Protein" or "11g Digestible Protein" would not be preempted, even though a claim about "11g Protein" is preempted. Citing three Ninth Circuit cases in accord, *Bell* explained that, "[a]bsent contrary language," the FDCA's express-preemption provision does not defeat state-law claims based on "deceptive statements that sellers add voluntarily to their labels or advertising." *Id.* at 484.[27]

Bell differs from these consolidated cases because the regulations at issue here include "contrary language" that directly addresses the kind of deception that Plaintiffs allege. Section 101.9(c)(7)(i) contemplates that advertising protein quantity outside the NFP can be misleading within the

[26] The *Bell* defendants made express-preemption and conflict-preemption arguments, *see* 982 F.3d at 483, but only the former are relevant to this case because the *Nacarino* and *Brown* Defendants assert only an express-preemption defense.

[27] In addition to *Durnford* and *Hawkins*, the Seventh Circuit cited our decision in *Astiana v. Hain Celestial Group, Inc.*, which held that the FDCA did not expressly preempt a claim that a cosmetics label's use of "natural" was deceptive where federal regulations did not address the use of "natural." 783 F.3d 753, 758 (9th Cir. 2015).

meaning of section 101.13(i)(3) if the manufacturer does not comply with the trigger provision's requirement to include a PDCAAS-corrected percent daily value figure in the NFP. *See* Food Labeling: Nutrient Content Claims, General Principles, Petitions, Definition of Terms, 56 Fed. Reg. 60421-01, 60426 (Nov. 27, 1991) (explaining that section 101.13(i)(3) addresses the concern that "a statement declaring that the product contained a specified amount of a nutrient could be misleading" when it gives consumers "the false impression that the product would assist them in maintaining healthy dietary practices relative to the amount of the nutrient consumed when it, in fact, would not").

The text and structure of the FDA regulations demonstrate that Defendants' protein claims could be misleading if they did not accurately state the quantity of protein (according to the analytical methodology prescribed in section 101.9(c)(7)) or the products did not display the quality-adjusted percent daily value in the NFP. But the *Nacarino* and *Brown* complaints did not allege that Defendants failed either to: (1) report accurately the quantity of protein on the front label pursuant to the nitrogen method; or (2) include the required percent daily value figure in the NFP as required by the trigger provision. We see no indication that Plaintiffs could have made these allegations with respect to the products listed in the complaints, and Plaintiffs have not suggested that the defects in their complaints could be cured by amendment. Plaintiffs' complaints do not allege that the challenged protein claims are misleading within the meaning of the federal regulations. To the extent that state law would hold Defendants to a different standard, Plaintiffs' claims are expressly preempted.

C

The regulations are not ambiguous and are sufficient to support our preemption holding, but the agency's interpretation of its own regulations reinforces that conclusion. We "may properly resort to an agency's interpretations and opinions for guidance, as they constitute a body of experience and informed judgment." *Hernandez v. Garland*, 38 F.4th 785, 789 (9th Cir. 2022) (quoting *Orellana v. Barr*, 967 F.3d 927, 934 (9th Cir. 2020)). We weigh agency interpretations according to their "power to persuade." *Skidmore v. Swift & Co.*, 323 U.S. 134, 140 (1944).[28]

Plaintiffs' complaints quote an agency memo that accompanied a final rule amending section 101.9(c)(7)'s rules for measuring and displaying protein content in the NFP. *See* Food Labeling: Mandatory Status of Nutrition Labeling and Nutrient Content Revision, Format for Nutrition Label, 58 Fed. Reg. 2079-01 (Jan. 6, 1993). The complaints reproduce only a single line from the memo, which included the FDA's observation that "[i]nformation on protein quantity alone can be misleading on foods that are of low protein quality." *Id.* at 2101. The rest of the memo more comprehensively explains the agency's reasoning. *See id.* at 2101–06. First, the FDA memo acknowledged comments it received that calculating PDCAAS scores for every product would "not provide flexibility" and would be "unnecessarily burdensome and expensive." *Id.* at 2104. The memo made clear that the agency did "not agree [with

[28] *See also Kisor*, 139 S. Ct. at 2416 ("[W]e have deferred to 'official staff memoranda' that were 'published in the Federal Register . . . .'" (quoting *Ford Motor Credit Co. v. Milhollin*, 444 U.S. 555, 566 n.9, 567 n.10 (1980))).

the comments] that the PDCAAS should be eliminated," *id*., but it did agree that a PDCAAS-adjusted score should not be required for all products because "protein deficiency is not common in the United States," even though "protein quality is still of concern for certain segments of the population," *id.* at 2102. The FDA ultimately determined that "nutrition labeling must allow consumers to readily identify foods with particularly low quality protein to prevent them from being misled by information on only the amount of protein present." *Id*.

In other words, the agency struck a balance that kept costs low for manufacturers without allowing consumers to be misled. It concluded that "the additional costs associated with determination of the PDCAAS, which are necessary to calculate the percent of the [daily recommended value] for protein, are not warranted on foods . . . *unless protein claims are made*." *Id.* (emphasis added). The memo explained that including the percent daily value in the NFP is "satisfactory" to "allow consumers to readily identify foods of low protein quality." *Id.* Section 101.9(c)(7)(i)'s trigger provision reflects this compromise, requiring information on protein quality in the NFP for products that manufacturers market to protein-conscious consumers, but not for labels that do not tout protein content outside the NFP. The FDA's consideration and rejection of a rule requiring PDCAAS-corrected percent daily value for every product provides additional support for our conclusion that a product's quantitative protein claims based on uncorrected values calculated using the nitrogen method are not false or misleading within the meaning of the regulations when PDCAAS-corrected percent daily value is included in the NFP.

Our conclusion is also supported by another source of agency guidance: an industry-facing FDA "Frequently-Asked-Questions" (FAQ) webpage.[29] The weight we may accord to this webpage "depend[s] upon the thoroughness evident in its consideration, the validity of its reasoning, its consistency with earlier and later pronouncements, and all those factors which give it power to persuade, if lacking power to control." *Skidmore*, 323 U.S. at 140. The webpage appears on the FDA's official website, and it states that it is intended to respond to "the most frequently asked questions [the FDA has] received." *Industry Resources*. The webpage does not purport to authorize nutrient content claims, but it does clarify the agency's view of how the front-label and NFP regulations interact, which is relevant to whether a nutrient content claim is authorized by section 101.13(i)(3):

> [Section Header:] Label Claims
>
> [Question:] There are separate methods for determining the number of grams of protein in a serving for declaration on the [NFP] and for determining the percent Daily Value of protein for the [NFP] (21 CFR 101.9(c)(7)). Which method should be used when calculating protein values for use in protein nutrient content claims?
>
> [Answer:] The regulation for nutrient content claims in 21 CFR 101.13(o) states that . . . compliance with requirements for nutrient

[29] *Industry Resources on the Changes to the Nutrition Facts Label*, U.S. Food & Drug Admin. (Jan. 11, 2022), https://www.fda.gov/food/food-labeling-nutrition/industry-resources-changes-nutrition-facts-label [https://perma.cc/FY86-VVH9] [hereinafter *Industry Resources*].

> content claims . . . will be determined using the analytical methodology prescribed for determining compliance with [NFP] labeling in 21 CFR 101.9.
>
> By design, 21 CFR 101.9(c)(7) specifically provides for two different methods for determining protein values. The regulation states, in 21 CFR 101.9(c)(7), that protein content may be calculated [using the nitrogen method]. Additionally, 21 CFR 101.9(c)(7)(ii) provides the method for determining protein content using [PDCAAS] for use in calculating the percent Daily Value [for display in the NFP].
>
> Determination of compliance for protein nutrient content claims will be based on the use of the methods provided in 21 CFR 101.9(c)(7), including either of the methods mentioned above.

Id. Because the definition of "nutrient content claim" excludes a statement made in the NFP, *see* 21 C.F.R. § 101.13(c), the webpage expresses the agency's guidance that quantitative protein claims based on the nitrogen method comply with the federal regulatory scheme, citing section 101.13(o) as a basis for this determination. Though not dispositive, the agency's webpage supports our view that federal law authorizes Defendants' challenged protein

claims. Having consulted the *Skidmore* factors, we find the interpretation on the agency's webpage persuasive.[30]

IV

The intricacy of the FDA's nutrition-labeling regulations reflects the agency's careful compromises among the diverse interests of its stakeholders. If Plaintiffs believe that a reasonable consumer would assume that all proteins are created equal, and that any products marketed as containing a certain quantity of protein provide identical protein-based health benefits, they are free to urge the FDA to amend the regulations or to challenge the agency's rules as inconsistent with its statutory mandate. In this case, sustaining Plaintiffs' challenge to Defendants' protein claims would indirectly establish a requirement for food labeling that differs from the federal requirements, so the FDCA preempts Plaintiffs' state-law claims. The district court properly dismissed the *Nacarino* and *Brown* complaints.

AFFIRMED.

[30] Defendants also argue that the district court erred by denying Kashi's request to take judicial notice of emails between industry lawyers and FDA officials. Unlike the Federal Register memo and the FAQ website, the agency's regulations disclaim that such statements reflect the FDA's official position or "otherwise obligate or commit the agency to the views expressed." 21 C.F.R. § 10.85(k); *see Maner v. Dignity Health*, 9 F.4th 1114, 1126 (9th Cir. 2021) (quoting *Kisor*, 139 S. Ct. at 2414).