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Rulings, FDA Guidance May Help Food Cos. In Protein Suits

By **Claudia Vetesi, Nicole Ozeran and Lena Gankin**
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Since spring 2020, food manufacturers have been hit with a wave of protein-labeling lawsuits all making the same core allegation: that their products' front-label protein content statements violate U.S. Food and Drug Administration regulations, and mislead consumers, by overstating the amount of protein in the food products.

Claudia Vetesi

While the plaintiffs admit that the FDA regulations are explicitly applicable to back-label claims, they allege that these same regulations do not apply to the same statements being made on front labels.

The defendants argue otherwise, claiming that the plaintiffs' proffered theory would result in the illogical result of having different protein statements on the front and back labels. And indeed,
the U.S. District Court for the Northern District of California, in a February ruling in Nacarino v. Kashi Co., described the applicable regulatory scheme as "convoluted."[1]

Nicole Ozeran

That was true — until recently. Earlier this year, the FDA released new guidance clarifying labeling requirements concerning protein claims, undermining the foundation of the labeling plaintiffs' claims. And the Northern District of California has since dismissed these protein lawsuits with prejudice.

These decisions highlight the dispositive impact of preemption arguments. But in two cases, plaintiffs have since appealed the district courts' orders dismissing their claims, bringing the regulatory scheme back into question.

Lena Gankin

District Courts' Distaste for Protein Suits

On Feb. 10, in Nacarino v. Kashi Co., Judge Vince Chhabria dismissed with prejudice the plaintiff's claims that Kashi mislabels its food products by miscalculating their protein content.[2]

The Nacarino court found that Kashi's use of the nitrogen method for calculating protein is appropriate under FDA regulations, and any claims brought by individuals based on the use of this method were

preempted by the Federal Food, Drug, and Cosmetic Act.[3] In making its ruling, the Nacarino court relied heavily on the FDA's newly issued guidance on its website clarifying appropriate methods for calculating front-label protein statements.

Less than a week after the Nacarino decision, another court in the Northern District of California followed suit, dismissing with prejudice the allegations of the plaintiff in Chong v. Kind LLC that Kind's front-label protein claims were deceptive and unlawful.[4]

In Chong, the court declined to follow its own earlier decision in what it admitted was a "nearly identical" lawsuit from 2020, Minor v. Baker Mills, which had permitted protein-labeling claims to proceed past a motion to dismiss.[5] The Chong court acknowledged that "it has now become apparent ... that Minor was incorrectly decided."[6]

Referencing Nacarino, the Chong court held that the plaintiff's claims were preempted because federal regulations establish "that producers may state grams of protein even outside the Nutrition Facts panel calculated by the nitrogen method, and without adjustment for digestibility."[7]

Furthermore, the court rejected plaintiff's claims based on Kind's failure to include a percentage of the daily value of protein on the back label, in violation of FDA regulations. The court found that, because they were entirely dependent on violations of the FDCA, the plaintiff's claims under California's Sherman Law were impliedly preempted under the U.S. Supreme Court's 2001 ruling in Buckman v. Plaintiffs' Legal Committee.[8]

The plaintiffs in both Nacarino and Chong have since appealed the courts' decisions dismissing their claims with prejudice.[9] Opening briefs are due in June, which will provide additional insight into the plaintiffs' basis for challenging the courts' conclusions that FDA guidance on protein claims is definitive.

FDA Regulations and New Guidance

Under FDA regulations, food manufacturers may calculate protein content for front-label protein claims at least two different ways: (1) calculating the amino acid content of the food directly, or (2) using the nitrogen method, which requires manufacturers to multiply the nitrogen content of the food by a factor of 6.25.[10]

When food manufacturers calculate the percentage daily value of protein on the product's back label, federal regulations require that the percentage be adjusted for digestibility using a "protein digestibility-corrected amino acid score."[11] Because plant-based proteins are not fully digestible by the human body, the amount of protein calculated under the nitrogen method may differ from the amount of protein as adjusted for digestibility and as used for calculating the percentage of daily value on the back label.

Plaintiffs have seized on these nuances in the federal regulations to argue that front-label protein claims overstate the amount of protein by failing to account for protein digestibility. In essence, plaintiffs claim that, despite manufacturers calculating protein claims in accordance with FDA regulations for back-label protein statements, using this same calculation for front-label claims is misleading.

But no requirement to calculate protein digestibility exists for front-label claims. In its Jan. 11 guidance, the FDA made it clear that, contrary to plaintiffs' claims, food manufacturers are not required to use only an amino acid content method for calculating front-label protein statements, nor are they required

to adjust the front-label content claims for digestibility.

Indeed, the FDA approves of the use of the nitrogen method for front-label protein claims, and does not require that manufacturers adjust protein content for digestibility when making such claims.

Looking Ahead

Where plaintiffs' claims rest on an interpretation of the federal regulatory scheme that the FDA recently rejected, decisions from the Northern District of California suggest that preemption arguments may present a viable defense — at least for now.

As the U.S. Court of Appeals for the Ninth Circuit grapples with Chong and Nacarino, manufacturers can expect some reprieve from the barrage of these protein case filings. Even if they are named in new filings, manufacturers have additional ammunition in their pockets, and should consider and give great weight to asserting preemption arguments and requesting a stay of their proceedings.

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[1] Nacarino v. Kashi Co., No. 21-cv-07036-VC, 2022 WL 390815, at *1 (N.D. Cal. Feb. 9, 2022).

[2] Id.

[3] Id. at *5.

[4] Chong v. Kind LLC, No. 21-cv-04528-RS, 2022 WL 464149 (N.D. Cal. Feb. 15, 2022).

[5] Id. at *1; Minor v. Baker Mills Inc., No. 20-cv-02901-RS, 2020 WL 11564643 (N.D. Cal. Nov. 12, 2020).

[6] Chong, 2022 WL 464149, at *1.

[7] Id. at *3.

[8] Id. at *4.

[9] Nacarino v. Kashi Co., No. 22-15377 (9th Cir.) (appeal filed March 14, 2022); Chong v. Kind LLC, No. 22-15368 (9th Cir.) (appeal filed March 11, 2022).

[10] See 21 C.F.R. § 101.9(c)(7).

[11] Id.