Bloomberg BNA

Product Safety & Liability Reporter™

FOOD

PREEMPTION

Preemption of consumer food labeling class suits is a mixed bag, and depends on the particular claim being challenged and the current regulatory activity, say attorneys Kara L. McCall, Elizabeth M. Chiarello and Laura A. Sexton. The authors discuss the treatment of challenges to eight different types of food labels, including ''Natural,'' ''Organic,'' ''Fat Free'' and ''Zero Calories.''

Federal Preemption of Food Labeling Claims



By Kara L. McCall, Elizabeth M. Chiarello and Laura A. Sexton

Food companies often face consumer challenges to their labeling claims—for example, ''all natural'' or ''no cholesterol.''

This article explains whether and when such challenges may be preempted by federal food labeling regulations.

Most often, if a plaintiff's labeling challenge is preempted, it will be because of the express preemption provided for issues regulated by the Nutrition Labeling and Education Act (NLEA).

The NLEA expressly preempts any state from directly or indirectly establishing requirements that are ''not identical'' to certain requirements established by federal law.[1] As another example, courts have held that the Organic Foods Production Act of 1990, 7 U.S.C. § 6513, preempts certain claims related to organic foods.

This article focuses less on *implied* preemption arguments, which are generally unsuccessful in this context—at least to the extent that they rely on the NLEA. The NLEA specifically states that it ''shall not be construed to preempt any provision of State law, *unless such provision is expressly preempted* under section [343-1(a)] of the [FDCA].''[2]

[1] 21 U.S.C. § 343-1.

[2] Pub. L. No. 101-535, § 6(c)(1), 104 Stat. 2353, 2364 (emphasis added). *See also Bruton v. Gerber Prods. Co.*, 961 F. Supp. 2d 1062, 1080-84 (N.D. Cal. 2013) (''The plain language of the statute, therefore, provides further evidence that

 ISSN 0092-7732

This article summarizes case law relating to preemption in the context of challenges to the following types of food label claims:

- ''Natural'' or ''All Natural''
- ''Organic''
- ''0g Trans Fats''
- ''Fat Free''
- ''No Cholesterol'' or ''Cholesterol Free''
- ''Zero Calories'' or ''Low Calorie''
- ''Sugar Free'' or ''No Sugar Added''
- ''Evaporated Cane Juice''

It is important to note that we are reporting on case law holdings and reasoning, which may or may not be consistent with the intentions of the regulators or the legislatures (or even the language of the laws).

'Natural' or 'All Natural'

The FDA has declined to define ''natural'' on several occasions.[3] Because of the FDA's inactivity in the area of ''natural'' labeling, preemption arguments related to ''natural'' claims used on food labeling generally have been unsuccessful.[4]

''Natural'' labeling challenges, however, may be preempted where the labels were pre-approved by the USDA,[5] or where ''natural'' is used to describe the flavoring, as opposed to the ingredients.[6]

'Organic'

Under the Organic Foods Production Act (''OFPA''), producers of agricultural products that market their products with the ''USDA Organic'' seal or that label their products as ''100 percent organic,'' ''organic,'' or ''made with organic'' ingredients, must be certified pursuant to OFPA's certification program. The certification program, through its implementing regulations, facilitates the accreditation of certifying agencies to review applications for organic certification.[7] A certifying agent may certify ''a farm or handling operation that meets the requirements of'' the OFPA and its implementing regulations.[8] Certification, which indicates regulatory compliance, is a prerequisite for organic labeling.[9]

Given the OFPA certification program, courts agree that the OFPA preempts state law claims challenging a defendant's *certification* as an organic producer.[10] OFPA also expressly preempts independent state certification laws unless they are approved by the USDA.[11]

Courts, however, disagree on preemption as a defense to claims challenging the use of ''organic'' labeling (as opposed to certification). The Eighth Circuit, on the one hand, has treated these claims as *de facto* challenges to a defendant's certification. Because a defendant's certification enables the sale of products with organic labeling, that court has reasoned that ''any attempt to hold [a producer] or the retailers liable under state law based upon its products supposedly not being

Kara L. McCall, a partner at Sidley Austin LLP's Chicago office, focuses on the defense of companies in class action litigation, product liability and mass torts, and complex commercial litigation. Elizabeth M. Chiarello, a partner in Sidley Austin's Products Liability practice in Chicago, and a member of the firm's Electronic Discovery Resource Group, focuses on the consumer products industry including companies that manufacture food, cosmetics, dietary supplements, and electronics. Laura A. Sexton is an associate in the Chicago office, practicing in the Product Liability & Mass Torts group. The authors are available at kmccall@sidley.com, echiarello@sidley.com and lsexton@sidley.com, respectively.

Congress did not intend for the FDCA, as amended by the NLEA, to impliedly preempt state-law food labeling claims.'').

[3] *See, e.g.,* 58 Fed. Reg. 2,302-01, 2,397 (Jan. 6, 1993) (''Because of resource limitations and other agency priorities, FDA is not undertaking rulemaking to establish a definition for 'natural' at this time.'').

[4] *See, e.g., Holk v. Snapple Beverage Corp.*, 575 F.3d 329 (3d Cir. 2009); *Ham v. Hain Celestial Grp., Inc.*, No. 14-cv-02044, Order [D.E. 33] (N.D. Cal. Oct. 3, 2014); *Dye v. Bodacious Food Co.*, No. 14-cv-80627, Order [D.E. 14] (S.D. Fla. Sept. 9, 2014); *Garcia v. Kashi Co.*, No. 12-21678-CIV (S.D. Fla. Sept. 5, 2014); *In re Hain Celestial Seasonings Prod. Consumer Litig.*, 8:13-cv-01757, Order [D.E. 34] (C.D. Cal. June 10, 2014); *Randolph v. J.M. Smucker Co.*, No. 13-80581-CIV (S.D. Fla. Mar. 14, 2014); *Werdebaugh v. Blue Diamond Growers*, No. 12-CV-02724 (N.D. Cal. Oct. 2, 2013); *In re Frito-Lay N. Am., Inc. All Natural Litig.*, No. 12-MD-2413 (E.D.N.Y. Aug. 29, 2013); *Astiana v. Ben & Jerry's Homemade, Inc.*, No. C 10-4387 (N.D. Cal. May 26, 2011); *Lockwood v. Conagra Foods, Inc.*, 597 F. Supp. 2d 1028 (N.D. Cal. 2009). *But see Astiana v. Hain Celestial Grp., Inc.*, 905 F. Supp. 2d 1013 (N.D. Cal. 2012) (dismissing UCL, FAL, and CLRA claims challenging ''natural'' labeling on *cosmetics* based on primary jurisdiction).

[5] *See Barnes v. Campbell Soup Co.*, No. C 12-05185 (N.D. Cal. July 25, 2013) (''100% Natural'' chicken soup claims preempted where label was pre-approved by USDA and FSIS).

[6] *See Lam v. Gen. Mills, Inc.*, 859 F. Supp. 2d 1097, 1101-03 (N.D. Cal. 2012).

[7] 7 U.S.C. § 6513.

[8] 7 U.S.C. § 6503(d).

[9] U.S.C. § 6505(a)(1)(A) (A person may only ''sell or label an agricultural product as organically produced'' if the product is produced in accordance with the OFPA and its implementing regulations); 65 Fed. Reg. 80548-01 (''Except for exempt and excluded operations, each production or handling operation or specified portion of a production or handling operation that produces or handles crops, livestock, livestock products, or other agricultural products that are intended to be sold, labeled, or represented as '100 percent organic,' 'organic,' or 'made with organic (specified ingredients or food group(s))' must be certified.'').

[10] *See In re Aurora Dairy Corp. Organic Milk Mktg. and Sales Practs. Litig.*, 621 F.3d 781, 792, 794-97 (8th Cir. 2010) (by enacting the OFPA, Congress sought to ''replace the patchwork of existing state regulations with a national standard defining organic food'' and ''to the extent state law permits outside parties, including consumers, to interfere with or second guess the certification process, the state law is an obstacle to the accomplishment of congressional objectives of the OFPA.'') (internal quotation marks omitted).

[11] 7 U.S.C. § 6507.

  PSLR ISSN 0092-7732

organic directly conflicts with the role of the certifying agent as set forth in § 6503(d).''[12]

In contrast, two courts in the Northern District of California have held that the OFPA does *not* preempt claims challenging ''organic'' labeling, as long as those claims do not challenge a certification made pursuant to the OFPA.[13] These courts distinguished the Eighth Circuit's holding in *Aurora* on the basis that it only preempted claims relating to the OFPA certification process.[14] However, this interpretation has been criticized,[15] and the express language of *Aurora* is not so narrow: ''To the extent the class plaintiffs, relying on state consumer protection or tort law, seek to set aside Aurora's certification, ***or seek damages from any party for Aurora's milk being labeled as organic in accordance with the certification,*** we hold that state law conflicts with federal law and should be preempted.''[16]

'0g Trans Fats'

Within the nutrition box, the trans fat content ''***shall*** be expressed as zero'' when a serving contains less than 0.5 grams trans fat.[17] Due to this specific and mandatory requirement, any claims challenging statements *within* the nutrition box are expressly preempted, 21 U.S.C. § 343-1, and plaintiffs rarely challenge such statements.[18]

When a ''0g Trans Fat'' or ''No Trans Fat'' statement is made *outside* the nutrition box, the amounts should mirror the values in the Nutrition Facts box.[19] Therefore, statements like ''0g Trans Fat'' and ''No Trans Fat'' should only be used when the nutrition box expresses the trans fat content as zero. Regarding other statements, FDA has not expressly permitted nutrient content claims—claims that characterize the level of a nutrient in the product—relating to trans fat content.[20] Therefore, while statements like ''0g Trans Fat'' may be acceptable because they mirror the nutrition box, other statements about trans fat content—*e.g.*, ''Low Trans Fats''—are not expressly permitted.

Accordingly, even when used outside the nutrition box, courts have found challenges to the use of ''0g Trans Fat'' or ''No Trans Fat'' statements to be expressly preempted under 21 U.S.C. § 343-1.[21] However, courts have held that challenges to trans fat claims are not preempted when they are based on *violations* of federal regulations.[22]

'Fat Free'

Within the nutrition box, total fat ''***shall*** be expressed as zero'' when there is less than 0.5 grams fat per serving.[23] As with trans fats, claims challenging statements *within* the nutrition box are expressly preempted, 21 U.S.C. § 343-1. Regarding nutrient content claims, the FDA has issued specific regulations that expressly permit—but do not require—the use of ''fat free'' claims in certain circumstances.[24] For example, a product *may* be labeled as ''fat free'' when it contains less than 0.5 grams of fat per serving, and per ''reference amount

[12] *Aurora*, 621 F.3d at 797. *See also Quesada v. Herb Thyme Farms, Inc.*, 166 Cal. Rptr. 3d 359 (2013) (a state law private right of action ''is preempted by Congress's mandate precluding private enforcement of the national organic standards to ensure national consistency in the production and labeling of agricultural products as 'organic.' ''), *review granted*, 323 P.3d 1 (Cal. Apr. 30, 2014) (review granted on whether the OFPA preempts state consumer lawsuits alleging that a food product was falsely labeled ''100% Organic'' when it contained ingredients that were not certified organic under the California Organic Products Act of 2003).

[13] *See Jones v. ConAgra Foods, Inc.*, 912 F. Supp. 2d 889, 894-96 (N.D. Cal. 2012) (California state law claims relating to ''organic'' and ''certified organic'' labeling were not preempted); *Brown v. Hain Celestial Grp., Inc.*, No. C 11-03082 (N.D. Cal. Aug. 1, 2012) (OFPA does not expressly preempt state law claims regarding ''organic'' cosmetics, noting that USDA guidance states that the agency ''asserts no authority over . . . 'organic' certification for personal care/cosmetics products'').

[14] *See Jones*, 912 F. Supp. 2d at 894-95; *Brown*, No. C 11-03082 (N.D. Cal. Aug. 1, 2012).

[15] *Quesada*, 166 Cal. Rptr. 3d

[16] 621 F.3d at 797 (emphasis added).

[17] 21 C.F.R. § 101.9(c)(2)(ii) (emphasis added).

[18] *See, e.g.*, *Chacanaca v. Quaker Oats Co.*, 752 F. Supp. 2d 1111, 1119-20 (N.D. Cal. 2010) (noting that plaintiff's claims only assert that the ''0 grams trans fat'' statement is misleading when ''removed from the nutrition box'').

[19] 58 Fed. Reg. 44020, 44024–25 (Aug. 18, 1993) (any discrepancy between a nutrient content claim and the Nutrition Facts panel would be ''confusing to consumers, and this consequence is unintended'').

[20] 21 U.S.C. § 343(r)(1)(A); 21 C.F.R. § 101.13 (''Nutrient content claims—general principles).

[21] *See Carrea v. Dreyer's Grand Ice Cream, Inc.*, 475 F. App'x 113, 115 (9th Cir. 2012) (unpublished) (claims regarding the ''0g Trans Fat'' statement located on the front of the packaging are expressly preempted because ''the Nutrition Facts panel must express [the trans fat] amount as zero,'' and ''the same rule applies to the statement on the front of [the] packaging''); *Young v. Johnson & Johnson*, No. CIV.A. 11-4580 (D.N.J. Apr. 19, 2012) (unpublished) (claims challenging ''No Trans Fat'' and ''No Trans Fatty Acids'' are expressly preempted, even though they appeared outside the Nutrition Fact box because ''FDA regulations provide that the same nutritional content claims authorized in the Nutrition Fact box can be repeated outside of that box and are subject to the same rules.'') *aff'd*, 525 F. App'x 179 (3d Cir. 2013); *Reid v. Johnson & Johnson*, No. 11CV1310 L (S.D. Cal. Sept. 18, 2012) (claims challenging ''No Trans Fat'' and ''No Trans Fatty Acids'' outside nutrition box were preempted because these statements were similar to the trans fat content disclosures within the nutrition box.); *Chacanaca*, 752 F. Supp. 2d at 1119-21 (claim challenging the placement of ''0 grams trans fat'' outside the nutrition box was preempted because FDA regulations required reporting zero grams of trans fat in the nutrition box and the agency has ''expressed a preference for internal consistency between the nutrition box and the rest of the label'' to avoid consumer confusion).

[22] *See, e.g., Wilson v. Frito-Lay N. Am., Inc.*, No. 12-1586 SC (N.D. Cal. Apr. 1, 2013) (plaintiffs' claims were not preempted because they were ''based on the theory that by not complying with the relevant federal law and regulations, defendants' labels mislead and deceive consumers.''); *Pardini v. Unilever U.S., Inc.*, No. 13-1675 SC (N.D. Cal. Jan. 22, 2014) (plaintiff's claims challenging ''0 g Trans Fat* Per Serving'' statement were not preempted because plaintiff alleged that defendant failed to comply with a disclaimer requirement applicable to certain nutrient content claims); *Reyes v. McDonald's Corp.*, No. 06 C 1604 (N.D. Ill. Nov. 8, 2006) (claim challenging accuracy of McDonald's representation that fries contained 6g trans fat was not preempted to the extent that plaintiffs' action was identical to the requirements of the NLEA).

[23] 21 C.F.R. § 101.9(c)(2) (emphasis added).

[24] 21 C.F.R. § 101.62(b).

customarily consumed'' and certain other requirements are met.[25]

Notably, with respect to milk products, California successfully petitioned FDA for an exemption from the NLEA express preemption provision.[26] California has set specific percentage requirements for the standard of identity for whole milk, lowfat milk, and skim milk, as opposed to the minimum and maximum values used by federal regulations. Because of California's exemption, these requirements are unlikely to be preempted by federal law.

If a plaintiff alleges that a ''fat free'' nutrient content claim *violates* these federal regulations, the claim is unlikely to be preempted. For example, the preemption defense was unsuccessful in two cases involving milk products that were labeled ''fat free'' despite allegedly containing more than 0.5 grams of fat, in violation of federal law.[27]

Challenges to ''fat free'' labels have also arisen in cases where a plaintiff alleges that the defendant used an inappropriately small serving size. For example, in a case involving I Can't Believe It's Not Butter!® Spray, the plaintiff alleged that the defendant improperly used a small serving size based on the reference amount for ''Fats and Oils: Spray Types.''[28] This serving size had less than 0.5 grams of fat, thereby allowing a ''fat free'' designation. However, the plaintiff argued that this ''fat free'' designation was improper because the defendant should have used a larger serving size based on the reference amount for butter alternatives, in which case each serving would have had more than 0.5 grams of fat.[29] Preemption of challenges like this one has turned on whether the defendant complied with serving size regulations.[30]

'No Cholesterol' or 'Cholesterol Free'

In certain circumstances, federal regulations permit ''cholesterol free'' or ''no cholesterol'' nutrient content claims.[31] Given these regulations, suits challenging ''cholesterol free'' labels are typically preempted, provided that the challenged label claim is permitted by federal regulations.[32]

'Zero Calories' or 'Low Calorie'

Within the nutrition box, the calorie content ''*may*'' be expressed as zero if a serving has fewer than five calories.[33] Outside the nutrition box, companies may also use nutrient content claims—*e.g.*, ''calorie free'' or ''low calorie''—in certain circumstances.[34] For example, a ''calorie free'' or ''zero calories'' label may be used when the food ''contains less than 5 calories per reference amount customarily consumed and per labeled serving'' and certain other requirements are satisfied.[35] Likewise, a ''low calorie'' label may be used when, among other things, the food ''does not provide more than 40 calories per reference amount customarily consumed.''[36] Claims challenging ''zero calorie'' or ''low calorie'' labels are unlikely to be preempted when a plaintiff alleges that the label was used in *violation* of federal law.[37]

'Sugar Free' or 'No Sugar Added'

The requirements for ''sugar free'' nutrient content claims are set forth in 21 C.F.R. § 101.60(c)(1). If a manufacturer chooses to label a food as ''sugar free,'' the label *must* display one of the following: (1) a statement that the food is ''low calorie'' or ''reduced calorie,'' provided the food qualifies as a low or reduced calorie food, and the statement complies with additional federal regulations; (2) ''a relative claim of special dietary usefulness'' made in accordance with federal regulations; or (3) a disclaimer that the food is ''not a reduced calorie food,'' ''not a low calorie food,'' or ''not for weight control.''[38]

Most courts have declined to find express preemption in ''sugar free'' cases, holding that plaintiffs were sim-

---

[25] 21 C.F.R. § 101.62(b)(1)(i).

[26] 7 U.S.C.A. § 7254 (granting California alone an exemption from, among other things, the federal standards of identity for whole milk, lowfat milk, and skim milk); *see also* 21 U.S.C.A. § 343-1(b) (allowing Secretary to grant exemptions from express preemption); 58 Fed. Reg. 2462 (regulations regarding state petitions for exemptions from preemption); *People ex rel. Lockyer v. Shamrock Foods Co.*, 11 P.3d 956, 959-60 (Cal. 2000).

[27] *See Koenig v. Boulder Brands, Inc.*, 995 F. Supp. 2d 274, 283-87 (S.D.N.Y. 2014); *Stewart v. Smart Balance, Inc.*, No. CIV.A. 11-6174 (D.N.J. June 26, 2012). *Cf. Kuenzig v. Kraft Foods, Inc.*, No. 8:11-CV-838-T-24 (M.D. Fla. Sept. 12, 2011), *aff'd*, 505 F. App'x 937, 938 (11th Cir. 2013) (most of plaintiffs' claims—with the exception of the little FTC claim—that challenged ''percent fat free'' labels were preempted because defendants complied with federal regulations governing ''percent fat free'' labeling.).

[28] *Pardini*, No. 13-1675 SC (N.D. Cal. Jan. 22, 2014).

[29] *Id.*

[30] *Compare Pardini* (plaintiffs' challenge to ''0 Fat'' and ''0 Calorie'' label was preempted because defendant's serving sizes complied with federal regulations) *with Allen v. ConAgra Foods, Inc.*, No. 13-CV-01279 (N.D. Cal. Sept. 3, 2013) (plaintiff's claims challenging ''zero fat'' and ''zero calorie'' label were not preempted because plaintiff adequately alleged that defendant violated serving size regulations).

[31] 21 C.F.R. § 101.62(d).

[32] *See, e.g., Red v. The Kroger Co.*, No. CV 10-01025 (C.D. Cal. Sept. 2, 2010) (''Given that federal regulations specify when the terms 'cholesterol free' can be used, Defendant's compliance with those regulations cannot be deemed to be 'false or misleading.' ''); *Yumul v. Smart Balance, Inc.*, No. CV 10-00927 (C.D. Cal. Mar. 14, 2011) (because plaintiff sought to enjoin defendant from placing a ''No Cholesterol'' label claim on its product, which ''the FDA regulations expressly permit[ted,] . . . a liability finding in this action would impose a requirement that is not identical'' to federal law, and plaintiff's claims were thus preempted) (internal quotation marks omitted); *Henderson v. Gruma Corp.*, No. CV 10-04173 (C.D. Cal. Apr. 11, 2011) (rejecting plaintiffs' theory that ''0 g cholesterol'' was misleading because it suggested that defendant's products were healthy, and holding that plaintiffs' claim was preempted because defendant complied with federal law).

[33] 21 C.F.R. § 101.9(c)(1) (emphasis added).

[34] 21 C.F.R. § 101.60(b).

[35] 21 C.F.R. § 101.60(b)(1).

[36] 21 C.F.R. § 101.60(b)(2).

[37] *See Allen* (holding claim challenging ''zero calorie'' label was not preempted where plaintiff adequately alleged a violation of serving size regulations). *Cf. Gustavson v. Wrigley Sales Co.*, 961 F. Supp. 2d 1100, 1110, 1124-25 (N.D. Cal. 2013) (claim challenging ''low calorie'' representation on defendant's website was preempted because website claims are not subject to 21 C.F.R. § 101.60, and therefore, plaintiff's claim did not allege a violation of federal regulations).

[38] 21 C.F.R. § 101.60(c)(1).

  PSLR ISSN 0092-7732

ply alleging violations of 21 C.F.R. § 101.60(c)(1), and were not attempting to impose any additional, nonidentical requirements.[39]

However, at least one court held that defendant's nutrient content claim complied with federal regulations, and the plaintiff's claim was therefore expressly preempted by the NLEA. In *Gustavson v. Wrigley Sales Co.*, No. 12-CV-01861 (N.D. Cal. Jan. 7, 2014), the plaintiff alleged that defendant's products, including Eclipse® gum, were improperly labeled ''sugar free'' in violation of federal regulations.[40] However, after reviewing FDA guidance regarding sugar-free labeling, the court concluded that defendant's labels complied with federal regulations.[41] Accordingly, the court dismissed plaintiff's second amended complaint as expressly preempted pursuant to § 343-1(a)(5).[42]

On a separate but related note, primary jurisdiction arguments in this context have been denied on two grounds: (1) the federal government has already addressed sugar-free labeling, and is not expected to revisit the issue soon; and (2) resolution of sugar-free labeling claim challenges does not require the FDA's scientific or regulatory expertise.[43]

'Evaporated Cane Juice'

Plaintiffs have challenged the practice of listing ''evaporated cane juice'' as an ingredient to describe sweeteners, such as sugar. FDA requires that ''Ingredients required to be declared on the label or labeling of a food . . . shall be listed by common or usual name.''[44] The ''common or usual name'' can be defined by common usage or regulation.[45] In 2009, the FDA published a document entitled ''Draft Guidance for the Industry: Ingredients Declared as Evaporated Cane Juice.''[46] In this Draft Guidance, the FDA indicated that it is false and misleading to list evaporated cane juice (''ECJ'') as an ingredient because ECJ ''is not the common or usual name of any type of sweetener,'' and ''because that term falsely suggests that the sweeteners are juice.''[47] FDA has also issued warning letters to producers cautioning against use of ECJ as an ingredient name.[48] Importantly, in March 2014, FDA announced it was reconsidering its 2009 Draft Guidance, and re-opened the comment period.[49]

In light of this recent FDA activity, primary jurisdiction arguments in the ECJ context have become increasingly successful. The case law is not uniform, but most courts have dismissed or stayed proceedings challenging ECJ labeling while the FDA reconsiders its Draft Guidance.[50]

Conclusion

While the strength of preemption arguments will depend on the unique facts of a particular case and the guidance provided by the FDA and USDA, a few predictions can be made:

- Preemption arguments are not likely to be successful in cases involving ''natural'' labeling.
- While courts disagree as to whether claims challenging ''organic'' labels are preempted, defendants may be able to argue that by enacting the OFPA, Congress sought to create a national standard for defining organic food, and consequently, private actions that interfere with or second guess this national standard are preempted.
- Primary jurisdiction arguments are likely to be successful in cases involving ''evaporated cane juice''

[39] *See Ivie v. Kraft Foods Global, Inc.*, No. C-12-02554 (N.D. Cal. Feb. 25, 2013) (refusing to dismiss plaintiff's ''sugar free'' claims because compliance with § 101.60(c)(1) ''is a factual issue inappropriate for resolution on a motion to dismiss on the pleadings, and plaintiff seeks to impose nothing more than the FDA requirements''); *Bruton*, 961 F. Supp. 2d at 1080 (plaintiff's claims were not preempted because ''the NLEA's preemption provision does not . . . prohibit states from enacting food labeling requirements that are identical to FDA requirements,'' and plaintiff's claims fell ''within the scope of the FDA's requirements.''); *see also Khasin v. Hershey Co.*, No. 5:12-CV-01862 (N.D. Cal. Nov. 9, 2012) (plaintiff's claims brought under state law provisions that mirrored the FDCA and federal regulations were not expressly preempted because ''complying with the demand requested by Plaintiff in this cause of action would not require that Defendant undertake food labeling or representation different from the provisions of the FDCA or the rules and regulations promulgated by the FDA'').

[40] *Id.*

[41] *Id.*, *citing* 58 Fed. Reg. 44020.

[42] *Id.*

[43] *See Bruton*, 961 F. Supp. 2d at 1084-86; *Brazil v. Dole Food Co., Inc.*, 935 F. Supp. 2d 947, 959-60 (N.D. Cal. 2013); *Ivie,* No. C-12-02554 (N.D. Cal. Feb. 25, 2013).

[44] 21 C.F.R. 101.4(a)(1).

[45] Draft Guidance for Industry: Ingredients Declared as Evaporated Cane Juice, (Oct. 2009).

[46] *Id.*

[47] *Id.*

[48] *See Swearingen v. Yucatan Foods, L.P.*, No. C 13-3544 (N.D. Cal. May 20, 2014).

[49] 79 Fed. Reg. 12507.

[50] *See Morgan v. Wallaby Yogurt Co., Inc.*, No. 13-cv-00296, Order [D.E. 72] (N.D. Cal. Nov. 5, 2014) (granting defendant's motion for reconsideration and staying action); *Saubers v. Kashi Co.*, 13-cv-00899, Order [D.E. 52] (S.D. Cal. Aug. 11, 2014); *Gitson v. Trader Joe's Co.*, No. 13-cv-01333, Order [D.E. 101] (N.D. Cal. Aug. 8, 2014) (staying action to see whether FDA revises Draft Guidance); *Figy v. Amy's Kitchen, Inc.*, No. 13-cv-03816, Order [D.E. 71] (N.D. Cal. July 7, 2014) (setting aside previously entered judgment, reopening action, and staying the action pursuant to the doctrine of primary jurisdiction); *Swearingen v. Santa Cruz Natural Inc.*, No. 3:13-cv-04291, Order [D.E. 47] (N.D. Cal. July 1, 2014); *Gitson v. Clover Stornetta Farms*, No. C-13-01517 (N.D. Cal. June 9, 2014) (granting defendant's motion for reconsideration and staying action because ''the FDA is currently involved in creating a new regulation concerning the subject of this lawsuit,'' and thus ''the FDA's position on the lawfulness of the use of ECJ on food labels is 'under active consideration by the FDA' ''); *Swearingen v. Yucatan Foods, L.P.*, No. C 13-3544 (N.D. Cal. May 20, 2014); *Swearingen v. Attune Foods, Inc.*, No. 13-cv-04541, Order [D.E. 34] (N.D. Cal. May 19, 2014); *Reese v. Odwalla, Inc.*, No. 13-CV-947 YGR (N.D. Cal. Mar. 25, 2014) (staying action because FDA re-opened comment period on Draft Guidance); *Hood v. Wholesoy & Co, Modesto Wholesoy Co. LLC*, No. 12-CV-5550-YGR (N.D. Cal. July 12, 2013) (granting motion to dismiss ECJ claims based on primary jurisdiction doctrine). *But see Leonhart v. Nature's Path Foods, Inc.*, No. 5:13-CV-0492-EJD (N.D. Cal. Mar. 31, 2014) (''where FDA policy is clearly established with respect to what constitutes an unlawful or misleading label, the primary jurisdiction doctrine is inapplicable because there is little risk that courts will undermine the FDA's expertise. . . . FDA's guidance suggests that the agency does not view the issue as unsettled and the claim is not precluded by primary jurisdiction doctrine.'').

ingredient listings—at least while the FDA reconsiders its 2009 Draft Guidance.

■ For claims challenging other types of label statements, preemption arguments will turn on whether the plaintiff can plausibly allege that the defendant *violated* applicable federal regulations. If a plausible violation cannot be alleged, the claim will likely be preempted by the NLEA express preemption provision, which expressly preempts any state from directly or indirectly establishing additional requirements that are ''not identical'' to certain requirements established by federal law.

  PSLR ISSN 0092-7732