There is a recent proliferation of slack fill litigation involving food products – both class and non-class suits. If you are a food manufacturer, distributor or seller, you need to be prepared to deal with these claims. A good starting point, particularly for manufacturers, is to analyze your food packaging designs to determine if and how you can defend them in court, and if not, how you can change your packaging to mitigate your risk against slack fill claims while also preserving the success of your brand. Successful slack fill claims can impose considerable risk, from injunctive relief that disrupts distribution and sales, including product recalls, to the often enormous expense of package design overhauls, which may require you to start all over your branding efforts, to the disgorgement of revenues from sales of violating products.

Slack fill is the difference between the actual capacity of a container and the volume of product contained therein – in other words, the empty space in the package. Most people envision the empty space – air – inside a bag of potato chips. But slack fill exists in many other packaged food products.

The purpose of slack fill statutes is to avoid consumer confusion over how much product the consumer is purchasing – to allow the consumer enough information – be it appropriate labeling and/or the ability to view the contents of the package – to make an informed decision when buying the product.

Federal Food, Drug, and Cosmetic Act (“FDCA”) regulation 21 C.F.R. § 100.100 is the federal slack fill regulation. California’s nonfunctional slack fill statute applicable to packaged food
products is Business and Professions Code § 12606.2, and like many state slack fill statutes, it mirrors 21 C.F.R. § 100.100.

Slack fill in and of itself is not illegal or misleading. What is prohibited is “nonfunctional” slack fill. “Slack fill in a package shall not be used as grounds to allege a violation of this section based solely on its presence unless it is nonfunctional slack fill.” Cal. Bus. & Prof. Code § 12606.2(d). “A container that does not allow the consumer to fully view its contents shall be considered to be filled as to be misleading if it contains nonfunctional slack fill.” Id., § 12606.2(c) (emphasis added.) Thus, slack fill statutes acknowledge that nonfunctional slack fill is not an issue when the consumer can clearly see how much product is in the container. Typically, this applies to containers made of transparent material, like a clear glass jar or a clear plastic bag. It does not apply to translucent materials that must be held up to light or to transparent containers with labels or graphics that impede the consumer’s clear view of the contents.

**What constitutes nonfunctional slack fill.** The “FDA advises that, in many products, a certain level of slack-fill has a functional purpose . . . and, therefore, can be justified even though some consumers may perceive it to be misleading.” U.S. Food & Drug Admin., *Misleading Containers: Nonfunctional Slack-Fill*, 58 FR 2957-01.

Nonfunctional slack fill is the empty space in a package that is filled to substantially less than its capacity for reasons other than any one or more of the following:

1. Protection of the contents of the package.
2. The requirements of the machines used for enclosing the contents in the package.
3. Unavoidable product settling during shipping and handling.
4. The need for the package to perform a specific function, such as where packaging plays a role in the preparation or consumption of a food, if that function is inherent to the nature of the food and is clearly communicated to consumers.
5. The fact that the product consists of a food packaged in a reusable container where the container is part of the presentation of the food and has value that is both significant in proportion to the value of the product and independent of its function to hold the food . . .
6. Inability to increase the level of fill or to further reduce the size of the package . . .
If any of these six “safe harbors” or exceptions applies, the slack fill is functional and permissible. However, these categories do not provide a “safe harbor” for packaging that is otherwise deceptively designed or labeled under § 403 of the FDCA.

Many products settle inside the package from being jostled during shipment or handled in stores. Various factors influence how much settling occurs, such as product size, shape, density and fragility. Product breakage is a major cause of settling. According to the FDA, insofar as the physical limitations of the product contribute to settling during shipping and handling, such slack fill is functional.

Some manufacturers utilize a common size package for different but related, or seasonal, food products that might result in different levels of slack fill due to the size or shape of the food, e.g., frozen vegetables, and/or how much they naturally settle after packaging. The FDA has stated that while it does not intend for § 100.100 to require manufacturers utilizing good manufacturing practices to change the physical characteristics of a food or to incur the cost of additional or more sophisticated packaging equipment, manufacturers need to use good judgment in determining whether and when to vary the size of their packaging and/or the amount of product used to fill the packages, to avoid nonfunctional slack fill. Id. at 2961; U.S. Food & Drug Admin., Misleading Containers; Nonfunctional Slack-Fill, 58 FR 64123, 64129 (Dec. 6, 1993). Many machines can be adjusted to accommodate different size packages and fill content.

As the FDA acknowledges, “consumer demand for convenience has led to the development of food products that may be cooked in, or eaten out of, the containers in which they are purchased.” U.S. Food & Drug Admin., Misleading Containers; Nonfunctional Slack-Fill, 58 FR at 2961 (Jan. 6, 1993). For instance, “[a] package of microwavable brownies may contain a disposable tray in which the product is both mixed and cooked. Thus, the package would need to be large enough to accommodate a tray whose size was based, in part, on the size of the cooked brownies, not the amount of dry mix in the container.” Id.

It is important to note that, according to the legislative history of the federal regulation, and in particular commentary from the FDA, any portion of the empty space in the package that does not serve the functional purpose of any of the safe harbors constitutes nonfunctional slack fill. U.S. Food & Drug Admin., Misleading Containers; Nonfunctional Slack-Fill, 58 FR 64123, 64126 (Dec. 6, 1993). For instance, if the box in which the brownies and tray are
packaged is larger than necessary to hold the tray, that unnecessary empty space would be considered nonfunctional. Similarly, if a package of frozen vegetables is designed to be used to steam the food in a microwave, but the package is larger than what is required to cook the vegetables, that extra empty space would be considered nonfunctional slack fill.

In other words, manufacturers need to optimize their packaging design so it is as efficient as possible and minimizes empty space. To do that, manufacturers also need to know the physical characteristics of the products and the capabilities (and limitations) of their packaging machinery.

**How do you analyze your packaging and optimize its design?** If you have in-house packaging expert capabilities, utilize them to analyze your packaging designs. If not, there are packaging consultants who can conduct such analysis. Typically, such analysis entails review of each SKU’s package design, including the manufacturing process (e.g., how the package is filled, what limitations the machines used have, and the level of product content), to assess how that process and the package design might be varied, if at all, to minimize slack fill. Testing is recommended, particularly if the package is used to cook the food. You also should consider how the product is typically handled and viewed by the consumer, how the product is to be distributed, transported, stored and displayed in stores or on the Internet, etc.

**Accurately stating the weight or volume of the product contents is, alone, not enough.** According to the FDA, accurately stating the net weight or volume of the contents of the package does not protect the consumer against misleading slack fill. Nonfunctional slack fill can still exist.

**Litigation considerations.** A couple of things to consider regarding existing or potential litigation:

1. **Privilege.** Should you cloak your package design analysis with the attorney-client privilege and/or attorney work product doctrine? If you doubt the outcome of the analysis will be favorable, you may want to do so. Of course, if the analysis is favorable, you may at some point want or need to waive those privileges in order to use that information to defend your packaging design.

2. **Evidentiary standards.** Regardless of how you address the privilege issue, you should ensure that you use a scientifically sound and accepted methodology for how you analyze and test your packaging designs so that such evidence is admissible under the applicable
evidentiary standards, such as the Daubert test used in federal courts. You don’t want to spend valuable resources on an expert consultant to validate your design and then not be able to get that evidence admitted in court.

Recent slack fill cases – mixed results. Decisions in slack fill litigation have been mixed, but the courts seem to be getting tougher on plaintiffs from a pleading standpoint, conducting a more rigorous analysis of their factual allegations to determine if they state valid slack fill claims, using a reasonable consumer standard. Prior decisions were much more lenient and held less factual allegations sufficed.

In Bush v. Mondelez Int’l, Inc., No. 16-CV-02460-RS, 2016 WL 5886886 (N.D. Cal. Oct. 7, 2016) ("Bush I") and Bush v. Mondelez Int’l, Inc., 2016 WL 7324990 (N.D. Cal. Dec. 16, 2016) ("Bush II"), the Northern District of California twice granted a motion to dismiss defectively pleaded slack fill claims. Plaintiff alleged that defendant’s Mini Chips Ahoy!, Mini Oreo, Golden Oreo Mini, Nutter Butter Bites, Mini Nilla Wafers, Ritz Bits, and Teddy Grahams contained nonfunctional slack fill. Bush I at *1. Mr. Bush argued that “the container size leads consumers to believe that there will be more snack food than there actually is” and that “he would not have purchased the products had he known the containers were not ‘adequately filled.’” Bush I at *4. “After reciting the six circumstances in which slack-fill is functional and not misleading, under 21 C.F.R. § 100.100(a)(1)-(6), [the plaintiff] allege[d] tersely that ‘none of these circumstances apply here.’” Bush I at *4. The court held these “allegations are insufficient to support a claim of unlawful packaging.” Id. (citing Victor v. R.C. Bigelow, Inc., No. 13-02976, 2014 WL 1028881, at *16 (N.D. Cal. Mar. 14, 2014) (“finding that a complaint consisting of ‘a litany of FDA regulations and federal statutes, and no factual allegation about how [the defendant’s] actions ... are either unlawful or fraudulent aside from conclusory statements ... do[es] not suffice for Rule 8’s ‘plausibility’ standard, let alone Rule 9’s ‘particularity’ standard for pleading”); Park v. Welch Foods, Inc., No. 12-06449, 2013 WL 5405318, at *5 (N.D. Cal. Sept. 26, 2013) (“dismissing amended complaint that provided ‘little more than a long summary of the FDCA and its food labeling regulations, a formulaic recitation of how these regulations apply to Defendants’ products, and conclusory allegations regarding Defendants’ ‘unlawfulness’”)). The court allowed plaintiff to amend his complaint. Plaintiff did so but continued to merely allege that none of the safe harbors under § 100.100 applied. The court granted defendant’s motion to dismiss without further leave to amend because the “allegations continue to be entirely conclusory” and plaintiff “ha[d] not amended them in any meaningful way.” Bush II at *4.
Courts in other districts have made similar holdings. See *Bautista v. Cytosport Inc.*, 2016 WL 7192109, at *5 (S.D.N.Y. Dec. 13, 2016) (holding “a plaintiff must possess some factual basis before bringing a [nonfunctional slack fill claim]” and dismissing the plaintiff’s conclusory allegations as insufficient to state a nonfunctional slack fill claim); see also *O’Connor v. Henkel Corp.*, No. 14-CV-5547 ARR MDG, 2015 WL 5922183, at *9 (E.D.N.Y. Sept. 22, 2015) (dismissing complaint where plaintiff alleged conclusory statements that the products contained slack fill and the packaging was “deceptive and misleading and was designed to increase sales” because “[s]uch conclusory statements are not entitled to the presumption of truth” and “there [were] no well-pleaded factual allegations . . . permitting [the] court to reasonably infer that defendants acted intentionally and systematically in under-filling their products”). In *Fermin v. Pfizer Inc.*, No. 15 CV 2133 (SJ) (ST), 2016 WL 6208291, at *1 (E.D.N.Y. Oct. 18, 2016), the court granted the defendant’s motion to dismiss because the plaintiffs failed to allege facts demonstrating that the “allegedly misleading packaging was ‘likely to mislead [or deceive] a reasonable consumer acting reasonably under the circumstances.’” *Id.* at *2 (citing *Freeman v. Time, Inc.*, 68 F.3d 285, 289 (9th Cir. 1995)). “The term ‘likely’ indicates that deception must be probable, not just possible.” *Id.* (citing *McKinniss v. Sunny Delight Beverages Co.*, No. CV 07–02034–RGK (JCx), 2007 WL 4766525, at *3 (C.D. Cal. Sept. 4, 2007).) “It is well settled that a court may determine as a matter of law that an allegedly deceptive practice would not have misled a reasonable consumer.” *Id.*

A reasonable consumer cannot suspend common sense or ignore other methods of observation such as feeling the contents of the package, or avoid reading the cooking instructions on the package. See *Workman v. Plum Inc.*, 141 F. Supp. 3d 1032, 1035 (N.D. Cal. 2015), appeal dismissed (Mar. 14, 2016) (granting defendant’s motion to dismiss without leave to amend, holding a reasonable consumer would be not be deceived by the labels at issue because “any potential ambiguity could be resolved by the back panel of the products” . . . and “reasonable consumers expect that the ingredient list contains more detailed information about the product that confirms other representations on the packaging.”). By picking up a bag and either feeling its contents or reading the package labeling, a reasonable consumer should, in many cases, be able to ascertain and understand that the package is not bursting at the seams with product and generally to what extent it is filled.

However, in *Leonhart v. Nature’s Path Foods, Inc.*, No. 13-CV-492, 2014 WL 6657809, at *7 (N.D. Cal. Nov. 21, 2014), the Northern District of California denied a motion to dismiss a class action asserting a variety of claims brought under California consumer protection
statutes, including a claim based on slack filled packaging. The plaintiff alleged that the defendant “routinely employed slack filled packaging containing non-functional slack fill to mislead consumers into believing they were receiving more than they actually were”; and that the plaintiff “purchased slack filled packages of EnviroKidz Panda Puffs and Heritage Flakes, and that she would not have done so had she realized that the packages were slack filled.” The court held “[t]hose allegations are sufficient to state a claim.”

One issue the courts have yet to squarely address is whether the safe harbors are affirmative defenses, or part of the definition of “nonfunctional slack fill” such that a plaintiff has to plead facts demonstrating that none of the safe harbors applies. Food manufacturers should argue that the safe harbors are part and parcel of the definition, and plaintiffs must plead such facts. By definition, if any of the safe harbors applies, slack fill in the package is functional and therefore permissible under the statute. See Cal. Bus. & Prof. Code § 12606.2(c). With the courts’ recent trend granting motions to dismiss slack fill claims, such an argument may be successful.

1. “The FDA advises that the exceptions to the definition of ‘nonfunctional slack-fill’ in § 100.100(a) apply to that portion of the slack-fill within a container that is necessary for, or results from, a specific function or practice, e.g., the need to protect a product. Slack-fill in excess of that necessary to accomplish a particular function is non-functional slack-fill. Thus, the exceptions in § 100.100(a) provide only for that amount of slack-fill that is necessary to accomplish a specific function. FDA advises that these exceptions do not exempt broad categories of food, such as gift products and convenience foods, from the requirements of section 403(d) of the act. For example, § 100.100(a)(2) recognizes that some slack-fill may be necessary to accommodate requirements of the machines used to enclose a product in its container and therefor is functional slack-fill. However, § 100.100(a)(2) does not exempt all levels of slack-fill in all mechanically packaged products from the definition of non-functional slack-fill.” Id.

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