CONSIDERATIONS FOR PACKAGING SUPPLIERS

Regarding the Declaration of Major Food Allergens and Gluten

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This memorandum accompanies Project Passport’s Guidelines for Risk Communication for the Global Food Contact Supply Chain and identifies our recommendations regarding the disclosure to downstream customers of major food allergens and gluten that may be present in food contact articles.

In general, the presence of allergenic proteins and gluten is rarely an issue for food contact materials as these substances are not commonly used in the manufacture of packaging itself. Nevertheless, customers may seek representations and assurances in this area; this memorandum is intended to assist food contact material suppliers with responding to such requests. In cases where an allergenic material or gluten may be present, companies must make sure to provide clear and accurate advice to their customers, as the implications of a mistake for labeling these materials may result in a recall of a customer’s product.

Regarding major allergens, there are two main considerations. First, when food contact articles may be formulated or manufactured with substances that may contain proteins derived from food allergens, there is the potential for these substances to migrate from the article to food and cause an allergic reaction in consumers of the food. Second, regardless of whether there is a risk of an allergic reaction, the U.S. Food and Drug Administration (FDA) could view the presence of these allergenic proteins as creating a labeling requirement under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). Failure to identify these substances on a product label could pose a significant recall issue for customers and brand owners. Due also to the serious consequences for brand owners if an allergenic substance migrates from an article to food, packaging suppliers must pay strict attention to the need to inform customers of the potential presence of these substances in their products.

Gluten is not a “major allergen” under FALCPA and thus is not subject to the mandatory declaration requirements referenced above. Nevertheless, some consumers are sensitive to the presence of gluten in the diet, and FDA regulations permit “gluten-free” labeling on finished foods to assist such consumers with selecting food options. In furtherance of such claims, packaging suppliers may receive questions from their customers regarding the incidental presence of gluten that could migrate from packaging to finished foods.

I. Regulatory Framework Applicable to Major Allergens

By way of background, FALCPA amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) to require more complete labeling of food allergens. The eight major food allergen groups, as defined in Section 201(qq)(1) of the FD&C Act, are:

- milk
- egg
- fish (e.g., bass, flounder, or cod);
- Crustacean shellfish (e.g., crab, lobster, or shrimp)
- tree nuts (e.g., almonds, pecans, or walnuts)
- wheat
- peanuts
- soybeans

The term “major food allergen” is defined to mean:

a. any food from the eight groups listed above; or
b. any food ingredient containing protein derived from a food in one of the eight groups listed above.2

No exemption from the definition of a “major food allergen” exists for incidental additives. Therefore, incidental additives that are present in finished food products and that bear, contain, or are derived from a

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2 Highly refined oils and ingredients derived from highly refined oils are exempt from the definition of “major food allergen,” even where such oils are themselves derived from major food allergens. FD&C Act § 201(qq)(2)(A).
major food allergen also must appropriately be labeled in compliance with FALCPA. If a company fails to accurately label a food product as required by FALCPA, the food is considered to be misbranded under Section 403(w) of the FD&C Act and may potentially be recalled. Failure to label allergens appropriately is one of the primary causes of recalls and FDA is very active in this area.

FALCPA does not clearly distinguish between allergens that may be intentionally used as food ingredients and those that may be present as “incidental additives.” Under FDA's regulations, incidental additives include “[s]ubstances migrating to food from equipment or packaging or otherwise affecting food that are not food additives as defined in section 201(s) of the act; or if they are food additives as so defined, they are used in conformity with regulations established pursuant to section 409 of the act.” Due to its broad scope and limited exemptions, FALCPA may be read to apply to packaging materials that are considered to be “incidental additives” even though potentially allergenic protein may be present at extremely low levels in food contact materials.

FDA has not established a de minimis level below which the presence of an allergen is considered unlikely to produce an allergic response or may be deemed insignificant for labeling purposes. The legislative history of FALCPA indicates that Congress intended FDA to adopt a reasonable standard for determining whether a food ingredient does not contain an allergenic protein and also for the Agency to provide guidance to industry on whether foods that contain allergenic protein would cause an allergic response. Although FDA has undertaken some in food. Consequently, there is no regulatory guidance available to companies on how to determine whether even extremely low levels of an allergen would cause an allergic response if the substance were to migrate from a food contact article to food.

When ingredients that are directly added to food are major food allergens, it is fairly straightforward for a company to decide how to identify these substances on the food label. With respect to food contact articles, however, the brand owner may not be aware of the potential presence of an allergenic substance in such materials. In some cases, food packaging suppliers may use substances that are derived from major food allergens as components of food contact materials that they produce. Alternatively, they may use these substances in the manufacturing process for other materials intended for use in contact with food. Some examples include soy lecithin, which is derived from soy; and casein, a protein found in milk. Even where such a substance may be present at extremely low levels, food contact material suppliers must carefully consider any obligation that they may have to inform downstream customers of the potential presence of these substances in their products.

If packaging material suppliers determine that their products may contain a major allergen, the default decision should be to disclose the presence of the allergen to the customers, leaving the ultimate decision regarding finished product labeling up to such parties. This recommendation is based on two considerations:

- there is no bright line rule to establish a de minimis level below which allergen labeling is not required; and
- the potential consequences for failure to disclose major allergens on a food label include the risk of a product recall and possible liability risks to the supplier.

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3 Failure to label an allergen could be either a Class I or Class II recall situation. The definitions of FDA’s recall classifications are available at https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm049070.htm (reproduced in relevant part below):
- **Class I recall:** a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
- **Class II recall:** a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences.


5 See S. REP. NO. 108-226 (2004), at page 7, available at: http://www.gpo.gov/fdsys/pkg/CRPT-108spt226/pdf/CRPT-108spt226.pdf (“The committee intends that the Secretary will provide guidance to industry on the information that would be useful for making a determination that foods that contain protein derived from one of the eight food allergens do not cause an allergic response that poses a risk to human health. The committee also intends that the Secretary provide an appropriate process for providing such information to the Secretary that minimizes the burden on the food manufacturer.”).

We further recommend that any decision not to disclose allergen-related information to a customer should be made with the full knowledge of a company’s legal counsel.

In some cases, based on the processing and denaturing of the allergenic protein or the extremely low levels of such protein present in a food contact material, it may be possible not to disclose the presence of a major allergen. As noted above, highly refined oils that are derived from any of the major food allergens and ingredients derived from these highly refined oils are exempt from FALCPA labeling because they are considered to be so highly processed that allergenic protein will not remain in the oil. For instance, many manufacturers use epoxidized soybean oil in the production of food contact materials. Provided that highly refined soybean oil is used to produce the epoxidized soybean oil—which is very likely to be the case—then epoxidized soybean oil also would be exempt from the definition of a “major allergen.” In certain cases, there may be sufficient information available on specific individual allergens to enable a company to make a science-based decision that the potential levels involved would not give rise to a risk of allergic reaction. We note that such determinations generally involve employing a substantial safety margin. Any such determination must be made on a case-by-case basis, considering the specific intended application of the food contact article and the available data regarding whether the specific allergenic protein involved could cause a reaction at the potential level of exposure. Particularly in the absence of regulatory guidance from FDA with respect to such determinations, companies must proceed with caution in this area. In our experience, some companies disclose the potential presence of the allergenic protein while providing their customers with their own exposure analysis to assist the customers in making the ultimate labeling determination.

II. Regulatory Framework Applicable to Gluten

Gluten refers to a group of proteins found in grains such as wheat, barley, rye, and triticale. Some members of the population suffer from celiac disease and are sensitive to the presence of gluten in the diet. Other individuals voluntarily seek to avoid gluten as a lifestyle choice. Gluten is not a “major allergen” under FALCPA, and thus its presence does not raise exactly the same safety and labeling concerns as those described above.

In 2013, FDA issued a final rule regarding “gluten-free” labeling for food products. Although companies that wish to make a “gluten-free” claim on food must comply with FDA’s regulation, the use of such a claim is voluntary and primarily is intended to enable sufferers of celiac disease to more easily identify food options. The failure to declare the presence of gluten in a food does not misbrand the food. Instead, a food is misbranded when it bears a “gluten-free” claim that does not comply with FDA’s regulation. Thus, food contact suppliers may be asked to provide information about the use/presence of gluten to assist customers who wish to make voluntary “gluten-free” claims. However, food contact suppliers have no affirmative obligation to provide information about the potential presence of gluten in food contact materials

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7 FD&C Act § 201(qq)(2)(A) of the FD&C Act. Although FDA does not further define the term “highly refined oil,” it is generally understood to mean oil that has been “refined, bleached, and deodorized.” S. REP. NO. 108-226, at page 7 (“Highly refined oils are intended to signify refined, bleached, deodorized (RBD) oils.”).

8 We understand that most soybean oil manufactured in the U.S. is “highly refined.” Cold-pressed (or expeller-pressed or expeller-pressed) soybean oil that may be found in natural food stores or gourmet food stores potentially is not a “highly refined” oil, but such oil typically is not used as an ingredient in further processed foods. See Food Allergy Research & Education (FARE), Soy Allergy, available at: http://www.foodallergy.org/allergens/soy-allergy; “Refined soybean oil not an allergen, say food scientists” (May 2, 2005), available at: http://www.foodnavigator-usa.com/R-D/Refined-soybean-oil-not-an-allergen-say-food-scientists.

9 78 Fed. Reg. 47154 (Aug. 5, 2013); 21 C.F.R. § 101.91. Under the regulation, a food is “gluten-free” if it is inherently free of gluten or if it does not contain an ingredient that is: (1) a gluten-containing grain; (2) derived from a gluten-containing grain that has not been processed to remove gluten; or (3) derived from a gluten-containing grain that has been processed to remove gluten if the use of that ingredient results in the presence of 20 ppm or more gluten in the food. Any unavoidable presence of gluten in the food must be less than 20 ppm.
Conclusion

In sum, there is no clear legal or regulatory basis on which food contact suppliers can conclude that FALCPA labeling is not triggered by the presence of major food allergens in food contact materials. As stated above, while in some cases it may be possible for food contact suppliers to determine that low levels of exposure to particular allergenic proteins will not trigger allergic reactions, FDA has not established safe threshold levels for major allergens in food. Until FDA has provided further guidance on this subject, we believe that food contact material suppliers should be extremely cautious when deciding not to disclose to their customers the presence of any substances derived from a major food allergen in their products. Any determination that specific substances do not pose a risk of allergic reaction, suggesting that there is no need to label the finished food under FALCPA, should be made on a case-by-case basis and with the involvement of companies’ legal counsel.

Although FALCPA labeling is not triggered by the presence of gluten in food contact materials, food contact suppliers nevertheless may be asked for information regarding the presence of gluten to support potential “gluten-free” claims on their customers’ finished food products. Assessing the potential presence of major allergens and of gluten involves separate determinations, as the two categories are not mutually exclusive. Although the deliberate use of major allergens and gluten in the production of food contact materials is uncommon, food contact suppliers should be aware of the applicable requirements and prepared to provide their customers with information about the presence of major allergens (to support mandatory labeling under FALCPA) and gluten (to support voluntary labeling under FDA’s regulation).

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