

CONTENTS

LEGISLATION, REGULATIONS AND STANDARDS

FDA Revokes GRAS Status of Partially Hydrogenated Oils	1
FDA Issues Allergen Labeling Guidance	2
U.S. Senate Agriculture Committee to Hold Hearing on Avian Flu Pandemic and Its Impacts	2
U.S. Codex Delegates Schedule Spices and Culinary Herbs Meeting	3
EU Parliament to Vote on Draft Law to Ban Cloned Animals in Food	3
EFSA Guidance Addresses “Strengthened” GM Risk Assessments	3

LITIGATION

Skinnnygirl® Plaintiffs Denied Class Certification	4
Claim Dismissal Affirmed in Twinings “Antioxidant” Lawsuit	5
Heinz Frozen Tater Tots and Fries Contain <i>Trans</i> Fats, Putative Class Action Alleges	6
Consumer Putative Class Action Targets McCormick’s Alleged Slack-Filled Pepper Tins	6
White-Chocolate False Ad Suit Filed Against Ghirardelli in Puerto Rico	6

OTHER DEVELOPMENTS

Public Health Attorney Publishes Report Condemning ASN’s Ties with Industry	7
TV Documentary Alleges Some French Cheeses Produced Without Fresh Milk	7

LEGISLATION, REGULATIONS AND STANDARDS

FDA Revokes GRAS Status of Partially Hydrogenated Oils

The U.S. Food and Drug Administration (FDA) has **issued** a determination revoking the generally recognized as safe (GRAS) status of partially hydrogenated oils (PHOs), “the primary dietary source of industrially-produced *trans* fatty acids.” To comply with the declaratory order, food and beverage companies must remove PHOs from products by June 18, 2018, or request food additive approval for specific uses of PHOs.

Concluding that there is no longer expert consensus as to the safe use of artificial *trans* fat in human food, FDA argues that the action is “expected to reduce coronary heart disease and prevent thousands of fatal heart attacks every year.” In the wake of its November 2013 tentative decision, the agency apparently received more than 6,000 comments from individuals, industry and trade associations, consumer groups, and government officials, the majority of which purportedly supported the reduction of *trans* fat in the food supply.

“Studies show that diet and nutrition play a key role in preventing chronic health problems, such as cardiovascular disease and today’s action goes hand in hand with other FDA initiatives to improve the health of Americans, including updating the nutrition facts label,” said FDA Center for Food Safety and Applied Nutrition Director Susan Mayne in a concurrent press release. “This determination is based on extensive research into the effects of PHOs, as well as input from all stakeholders received during the public comment period.”

The agency also clarifies that the determination is a partial response to citizen petitions submitted by the Center for Science in the Public Interest (CSPI) and University of Illinois Professor Fred Kummerow, who sued the agency in 2013 over its failure to act on his submission. As CSPI Executive Director Michael Jacobson commented, “The final

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 569 | JUNE 19, 2015

determination made today by the Food and Drug Administration gives companies more than enough time to eliminate the last of the partially hydrogenated oil that is still used in foods like microwave popcorn, biscuits, baked goods, frostings, and margarines... If FDA approves it for use as a food additive, it must do so only in the tiniest of amounts.” See *The Washington Post* and *CSPI Press Release*, June 16, 2015.

FDA Issues Allergen Labeling Guidance

The U.S. Food and Drug Administration (FDA) has **announced** the availability of industry guidance on food allergen labeling exemptions. Titled “Food Allergen Labeling Exemption Petitions and Notifications,” the guidance reportedly explains the agency’s “current thinking on the preparation of regulatory submissions for obtaining exemptions for ingredients from the labeling requirements for major food allergens in the Federal Food, Drug, and Cosmetic Act (FD&C Act) through submission of either a petition or a notification.”

The guidance aims to clarify the criteria for labeling exemption petitions submitted under the Food Allergen Labeling and Consumer Protection Act of 2004, which requires all food and beverage labeling to declare the presence of major food allergens using their common names. Under these rules, companies can obtain labeling exemptions by demonstrating that an ingredient derived from a major allergen “does not cause an allergic response” or “does not contain allergenic protein.” See *Federal Register*, June 19, 2015.

U.S. Senate Agriculture Committee to Hold Hearing on Avian Flu Pandemic and Its Impacts

Following a request from Iowa Senators Joni Ernst (R) and Chuck Grassley (R), the U.S. Senate Committee on Agriculture, Nutrition and Forestry will convene a hearing on July 7, 2015, to discuss the ongoing outbreak of highly pathogenic avian influenza (HPAI), H5N2. The outbreak has “decimated” turkey, chicken and other poultry flocks in 15 states, and an estimated 30 million birds in Iowa have been affected.

“This is an important opportunity to bring leaders and key stakeholders together to review the pandemic spread of this deadly disease, identify areas for improvement within response procedures, and set the state to ensure we are better prepared in the future,” Ernst was quoted as saying.

Shook offers expert, efficient and innovative representation to clients targeted by food lawyers and regulators. We know that the successful resolution of food-related matters requires a comprehensive strategy developed in partnership with our clients.

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If you have questions about this issue of the *Update* or would like to receive supporting documentation, please contact Mary Boyd at mboyd@shb.com.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 569 | JUNE 19, 2015

Increases in wholesale table egg prices have reportedly “begun to reverse due to buyer resistance and limited demand,” according to the agriculture department’s Agricultural Marketing Service. *See Press Release of Sen. Charles Grassley*, June 11, 2015; *The New York Times*, June 16, 2015.

U.S. Codex Delegates Schedule Spices and Culinary Herbs Meeting

The U.S. Department of Agriculture’s Office of the Under Secretary for Food Safety and the Agricultural Marketing Service have **announced** an August 19, 2015, public meeting in Washington, D.C., to discuss draft U.S. positions for consideration at the 2nd Session of the Codex Committee on Spices and Culinary Herbs (CCSCH) slated for September 14-18 in Goa, India. The CCSCH sets global standards for dried and dehydrated spices and culinary herbs in whole, ground, cracked or crushed form. Agenda items at the August meeting include proposed draft standards for black, white and green pepper as well as cumin and oregano. *See Federal Register*, June 17, 2015.

EU Parliament to Vote on Draft Law to Ban Cloned Animals in Food

The Environment and Agriculture committees of the European Parliament have approved a draft bill that would ban the cloning of all farm animals, their descendants and products derived from them. The legislation would prohibit both the cloning within the EU and the importation of cloned animals from other countries. “We are well aware that cloning is allowed in certain third countries that EU trades with, but we cannot allow these products to be placed on the EU market,” Guilia Moi, an Italian Member of the European Parliament, said in a **press release**. “We also want to ensure that cloning of animals would not become a common practice within the EU.”

The proposed law would require the import certificates for animals, animal germinal products, food and feed of animal origin to indicate that the products are not derived from cloned animals. The European Parliament will vote on the bill at a plenary session slated for September 7-9, 2015. *See European Parliament Press Release*, June 17, 2015.

EFSA Guidance Addresses “Strengthened” GM Risk Assessments

The European Food Safety Authority’s (EFSA’s) Scientific Committee has **published** guidance for renewing “applications of genetically modified [GM] food and feed authorized under Regulation (EC) No. 1829/2003.”

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 569 | JUNE 19, 2015

Describing “the data requirements for renewal applications, “ the guidance directs applicants seeking reauthorization of GM food and feed products to provide the following: (i) “a copy of the authorization”; (ii) “post-market monitoring and post-market environmental monitoring reports”; (iii) “systematic search and evaluation of literature”; and (iv) “updated bioinformatics and any additional documents or studies performed by or on behalf of the applicant during the authorization period.” In addition, EFSA asks applicants “to assess the collected information and conclude whether the previous risk assessment remains valid.”

“GM food and feed listed under Regulation (EC) 1829/2003 are within the scope of this new guidance. These include all those plants that have already been assessed by EFSA—such as maize, oilseed rape, soybean and cotton,” explains a member of EFSA’s Panel on Genetically Modified Organisms in a June 18, 2015, news release. “It is important to point out that these authorizations are for the import or processing of GM food or feed, not for the cultivation of the GM plant.”

LITIGATION

Skinnygirl® Plaintiffs Denied Class Certification

A New Jersey federal court has again denied class certification to a trio of women suing Beam Global Spirits & Wine for allegedly misrepresenting Skinnygirl® Margaritas as using “only natural ingredients” despite containing sodium benzoate. *Stewart v. Beam Global Spirits & Wine, Inc.*, No. 11-5149 (D.N.J., order entered June 8, 2015). Details about the court’s previous examination of certification appear in Issue [529](#) of this *Update*.

The plaintiffs argued that the class could be ascertained through a three-level screening process designed to limit the number of fraudulent claims. The process would require potential claimants to provide a (i) claim form and receipt for the purchase of the product or (ii) a sworn affidavit with the dates, locations and prices of their Skinnygirl® Margarita purchases as well as a description of the bottle. In the latter case, the screeners would then check the potential claimants’ affidavits for accuracy to determine, for example, if the retailers listed actually sold the product at the cited times.



FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 569 | JUNE 19, 2015

Rejecting the plaintiffs' approach, the court found that the proposed screening was administratively unfeasible and unreliable. Most of the potential class members probably have not kept their receipts, the court noted, and even if they had, the screeners could not determine if the same receipt had been used for multiple claims. Further, true potential claimants may forget information required by the affidavits, while fraudulent claimants could gather the information for a claim without actually purchasing a bottle of the product. The plaintiffs also could not show that the method was reliable, the court found, because it had only been used to determine potential claimants in class actions that had already been settled.

Skinnygirl and a consumer settled a similar lawsuit in May 2015 after an Illinois federal court refused to certify the proposed class on similar grounds. Details about that stipulation appear in Issue [564](#) of this *Update*.

Claim Dismissal Affirmed in Twinings "Antioxidant" Lawsuit

A California federal court has confirmed its ruling that a plaintiff in a class action against Twinings North America cannot pursue her claim of unjust enrichment because it duplicates her consumer protection claims. *Lanovaz v. Twinings N. Am.*, No. 12-2646 (N.D. Cal., order entered June 10, 2015). Details about the court's previous rulings narrowing the claims and certifying an injunctive class appear in Issues [485](#) and [521](#) of this *Update*.

In her complaint, the plaintiff alleged that Twinings misbranded its green, black and white teas as a "natural source of protective antioxidants" despite failing to meet U.S. Food and Drug Administration standards for nutrient content claims. The court certified an injunctive class but denied the plaintiff's unjust-enrichment claim. The plaintiff, seeking certification for a damages class through that claim, filed a motion for reconsideration arguing that the damages available through the unjust-enrichment claim were different from the damages available via the consumer-protection claim, the basis for the injunctive class certification. The court disagreed, finding that the consumer-protection claim offered the same possible damages awards, and it had chosen not to certify the damages class. Accordingly, it denied the motion for reconsideration, and the case will continue as an injunctive-class-only action.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 569 | JUNE 19, 2015

Heinz Frozen Tater Tots and Fries Contain *Trans* Fats, Putative Class Action Alleges

A consumer has filed a putative class action against H.J. Heinz Co. alleging that the company's frozen microwave French fries and tater tots contain partially hydrogenated oil (PHO), which contains artificial *trans* fat, despite packaging that indicates the products contain "0g trans fat." *Backus v. H.J. Heinz Co.*, No. 15-2738 (N.D. Cal., filed June 18, 2015). The complaint asserts that any intake of *trans* fat is unsafe and cites the U.S. Food and Drug Administration's June 16, 2015, final determination that PHOs are not generally recognized as safe for any human food. The complaint further argues that the artificial *trans* fats in PHO cause several medical conditions such as cardiovascular disease, type 2 diabetes and Alzheimer's disease. The plaintiff alleges violations of California unfair competition, false advertising and consumer legal remedies statutes and seeks class certification, damages, disgorgement of benefits, an injunction, and attorney's fees.

Consumer Putative Class Action Targets McCormick's Alleged Slack-Filled Pepper Tins

Echoing a lawsuit brought a week earlier by a competitor in the pepper category, a consumer has filed a proposed class action against McCormick & Co. alleging that the company underfills its tins of black pepper because it reduced the pepper in each tin by 25 percent but retained the traditional packaging size. *Dupler v. McCormick & Co.*, No. 15-3454 (E.D.N.Y., filed June 15, 2015). Facing rising prices for black pepper, the complaint argues, McCormick has begun selling 1.5-ounce, 3-ounce and 6-ounce pepper products in place of its 2-ounce, 4-ounce and 8-ounce products, respectively, but continues to use the larger "iconic" packaging it used for decades. This "slack fill" violates the Food, Drug, and Cosmetic Act, the plaintiff argues, and she seeks to represent a New York class in an action for damages, an injunction and attorney's fees. The unfair-competition suit against McCormick alleging violations of the Lanham Act and various state business practices was discussed in Issue [568](#) of this *Update*.

White-Chocolate False Ad Suit Filed Against Ghirardelli in Puerto Rico

A consumer has filed a putative class action against Ghirardelli alleging that the company deceptively advertised its white-chocolate products as containing chocolate, white chocolate or cocoa butter. *Vega-Encarnacion*

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 569 | JUNE 19, 2015

v. Ghirardelli Chocolate Co., No. 15-1821 (D.P.R., filed June 16, 2015). Three of the products at issue in the complaint were the subjects of an October 2014 class action settlement open only to consumers who purchased the product “in the United States,” so the Puerto Rican consumer seeks to represent those similarly situated in U.S. territories. Additional details about the settlement appear in Issue [540](#) of this *Update*.

The complaint cites the U.S. Food and Drug Administration’s (FDA’s) definitions of “chocolate” and “white chocolate,” which include required levels of cacao-derived products such as cocoa butter. Ghirardelli’s white-chocolate products—baking chips, confectionary coating wafers and ground white chocolate flavor—do not contain any white chocolate as defined by FDA, but merely white-chocolate flavoring, the plaintiff argues. He seeks class certification, an injunction and damages for his allegations of breach of warranty and unjust enrichment.

OTHER DEVELOPMENTS

Public Health Attorney Publishes Report Condemning ASN’s Ties with Industry

“In order to bolster its credibility, reflect objective science that has the public’s best interest in mind, and hold the food industry more accountable, it is paramount that ASN reconsider its financial ties to the junk food industry,” concludes public health lawyer and activist [Michele Simon](#) in an [investigation](#) that purports to expose conflicts of interest between the American Society for Nutrition (ASN) and various food and beverage companies. Among other things, Simon contends that “powerful junk food companies purchase ‘sustaining partnerships’ from ASN, gaining access to the nation’s leading nutrition researchers at their annual meetings, and in their policy positions.”

TV Documentary Alleges Some French Cheeses Produced Without Fresh Milk

French restaurateurs and food critics are calling for new food-labeling rules after a documentary airing on France 2 reported that some of the country’s food manufacturers have been using vegetable-fat-based substitutes for fresh milk when producing cheese products. In “Artificial Cheese on Your Plate” (“*Du Faux Fromage Dans Votre Assiette*”), cheese producers are reportedly shown stocking bags of processed cheese made

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 569 | JUNE 19, 2015

ABOUT SHOOK

Shook, Hardy & Bacon is widely recognized as a premier litigation firm in the United States and abroad. For more than a century, the firm has defended clients in some of the most substantial national and international product liability and mass tort litigations.

Shook attorneys are experienced at assisting food industry clients develop early assessment procedures that allow for quick evaluation of potential liability and the most appropriate response in the event of suspected product contamination or an alleged food-borne safety outbreak. The firm also counsels food producers on labeling audits and other compliance issues, ranging from recalls to facility inspections, subject to FDA, USDA and FTC regulation.



with water, vegetable fat, lactic acid, table salt, and potassium sorbate, while others are shown mixing genuine mozzarella with cheese made without milk to create a popular substitute known as “50-50.” Many of the cheese substitutes also contain palm oil. A nutritionist told the documentary producers that the cheese substitutes lack the positive qualities of real cheese because they contain saturated fat without providing calcium as well. *See The Daily Telegraph*, June 14, 2015.