Shook, Hardy & Bacon L.L.P.

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# FOOD & BEVERAGE LITIGATION UPDATE

CONTENTS



## LEGISLATION, REGULATIONS AND STANDARDS

### FDA Issues Industry Guidance on Acrylamide Reduction

The U.S. Food and Drug Administration (FDA) has issued draft guidance for the food industry "to help growers, manufacturers and food service operators take steps to reduce levels of acrylamide in certain foods." A chemical formed in some foods during high-temperature cooking, acrylamide has been characterized by the National Toxicology Program as "reasonably anticipated to be a human carcinogen." Suggesting "a range of possible approaches to acrylamide reduction," the draft guidance stops short of identifying a specific maximum level or action level for acrylamide, but includes recommendations for potato-based foods, cereal-based foods and other products.

To reduce acrylamide formation during the cooking process, the draft guidance addresses what types of raw ingredients to use; how to transport, handle, store, and process ingredients; and how to prepare both fresh and par-cooked ingredients. In particular, FDA recommends, among other things, that the food industry (i) use certain kinds of potatoes and grains, e.g., tubers low in reducing sugars that have achieved optimal maturity and low-asparagine wheat; (ii) increase potato peel removal, wash potato chips before frying and cut thicker potato chip slices; (iii) add calcium salts, acidulants or asparaginase to potato dough in fabricated potato products; (iv) decrease cooking temperatures for potato products; (v) replace ammonium bicarbonate in cookies and crackers with alternative leavening agents; (vi) replace reducing sugars with non-reducing sugars in cereal-based foods; (vii) modify baking time and temperature to lower thermal input; and (viii) provide adequate instructions on frozen foods to guide final preparation by consumers and food service operators.

According to a November 14, 2013, press release, FDA plans "to publish additional data on acrylamide levels in certain foods based on its recent data collection and analysis." The agency will accept comments on the draft guidance until January 14, 2014. *See Federal Register,* November 15, 2013.

In a related development, the European Commission recently published recommendations stemming from its investigation of acrylamide in food. According to the Commission, the European Food Safety Authority (EFSA) and member states have monitored acrylamide levels in food since 2007 in

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 504 | NOVEMBER 15, 2013

SHB 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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addition to working with food industry stakeholders to minimize the amount of acrylamide measured in their products. Noting that a 2010 EFSA report found no consistent trend toward lower acrylamide levels across food groups, the Commission has replaced its 2011 recommendation with new indicative values for acrylamide that will trigger further investigation by regulators.

To this end, the recommendations include the following indicative values for acrylamide (i) 600 µg/kg for ready-to-eat french fries; (ii) 1,000 µg/kg for potato-based crackers, potato crisps and potato dough; (iii) 80 µg/kg for wheat-based soft bread and 150 µg/kg for other soft breads; (iv) 400 µg/kg for bran and whole grain cereals; (v) 500 µg/kg for biscuits and wafers; (vi) 450 µg/kg for roast coffee and 900 µg/kg for instant coffee; and (vii) 200 µg/kg for biscuits and rusks intended for infants and young children. The Commission also clarified that these levels were not safety thresholds, adding that investigations into acrylamide levels should include the food business operator's Hazard Analysis and Critical Control Points procedures "with a view to exploring… whether relevant processing steps susceptible for the formation of acrylamide have been identified and whether appropriate measures have been taken to control them."

In the interim, the Commission has directed member states to continue monitoring "the production and processing methods used by food producers in cases where the level of acrylamide in foodstuff… exceeds the acrylamide indicative value for the respective food category." Member states will report their findings to the Commission by October 31, 2014, and April 30, 2015, for further evaluation. *See the Official Journal of the European Union,* November 12, 2013.

### FDA Seeks Comments on Standards for Anti-*Salmonella* Chemical Food Additives

The U.S. Food and Drug Administration (FDA) has **issued** a request for comments on proposed revisions to its "Guidance for Industry: Studies to Evaluate the Utility of Anti-*Salmonella* Chemical Food Additives in Feeds." With the aim of helping sponsors design efficacy studies to support the submission of food additive petitions (FAPs) related to preventing *Salmonella* in food for animals, FDA noted that a revision is necessary because science, technology and FDA policy have changed since the guidance was last revised.

Because current guidance addresses only chemical food additives intended to maintain feeds or feed ingredients as *Salmonella*-negative, the agency intends to expand the scope to address other categories of food additives beyond chemical food additives and to cover all food for animals, including pet food.

Among other things, FDA seeks comment on the following questions: (i) what intended technical effects will the agency see in FAPs for anti-*Salmonella* use of the food additives in food for animals; (ii) how should efficacy studies

be designed for the intended technical effects; (iii) should experimental lots of animal food used in laboratory and field studies be *Salmonella*-negative, but not sterile, before inoculation; (iv) what inoculation levels of *Salmonella* are appropriate for experimental lots of animal food used in laboratory and field studies; (v) what methods should be used to inoculate experimental lots of animal food used in laboratory and field studies; (vi) what sampling criteria should be used; and (vii) what methods should be used to enumerate the level(s) of *Salmonella* in animal food? Comments will be accepted until January 13, 2014. *See Federal Register,* November 14, 2013.

**EFSA Reviews Study Linking Phosphate Additives to Cardiovascular Risk**

The European Food Safety Authority (EFSA) has **issued** a statement finding that a published review of observational studies ultimately failed to establish a causal relationship between high intakes of phosphate additives in food and increased cardiovascular risk in the general population. In addition to considering the data on the association between serum phosphate levels and cardiovascular disease, the review in question apparently proposed a mechanism by which the metabolism of inorganic phosphate could contribute to vascular calcification, in the process suggesting that "intake of phosphate as a food additive, especially through consumption of processed and ready-to-eat food, is of particular concern." Additional details about the review, which was initially published in the January 2012 edition of *Deutsches Ärzteblatt International,* appear in Issue **428** of this *Update*.

After assessing these findings at the request of the European Commission, EFSA concluded that (i) the limitations of the observational studies included in the review made it impossible "to make causal inferences for serum phosphate levels and the observed adverse effects," and (ii) the evidence did not make it clear "whether the increased cardiovascular risk observed in these observational studies is attributable to differences in the dietary intake of phosphorus in general or in the form of phosphate additives and serum phosphate levels." As a result, the agency suggested that "a meta-analysis of a systematic review of the available literature" could help resolve the current inconsistencies in studies examining the link between phosphate additives and cardiovascular disease.

"As set out by Regulation (EU) No 257/2010, phosphates for use as food additives will be re-evaluated by EFSA with high priority by 31 December 2018," concludes EFSA's statement. "In the context of this re-evaluation all relevant toxicological information will be collated and evaluated. A dedicated call for data aimed at gathering information on usage levels of phosphates in food will be launched in preparation for the re-evaluation."

### Maine's GM Bill Threatened by N.H. Lawmakers

Legislation (H.B. 660) in Maine that would require food manufacturers to label products containing genetically modified (GM) ingredients is reportedly in jeopardy after New Hampshire lawmakers voted 12-8 against a similar labeling bill. Although Maine's law passed earlier this year with broad bipartisan support, it can take effect only if five contiguous states pass similar laws.

"I was not surprised," said the New Hampshire bill's sponsor Maureen Mann (D-Deerfield) in a news article. Evidently, while a subcommittee that spent the summer working on the bill recommended its approval, members of New Hampshire's House Environment and Agriculture Committee expressed reservations about the measure, citing difficulties with enforcement because food labeling is a federal matter.

According to sources, unlike in Maine, the vote in New Hampshire broke along party lines, with Republican committee members largely opposing it. Democrats have a 42-vote majority in the New Hampshire House, while Republicans have a two-seat advantage in the Senate.

"It became more partisan in New Hampshire," said Rep. Lance Harvell (R-Farmington), the lead sponsor of the Maine bill. "It definitely makes things a lot tougher for our side." According to Harvell, industry groups that oppose labeling laws were better prepared in New Hampshire than in Maine and Connecticut, the first two states to pass such legislation. Despite the vote, the New Hampshire bill is not dead, and it will be considered by the full House during the next legislative session. *See Portland Press Herald,* November 13, 2013; *TheWireNH.com,* November 14, 2013.

### OEHHA's Carcinogen Committee to Consider Plasticizer Chemicals

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has issued the tentative agenda for the December 5, 2013, meeting of its Carcinogen Identification Committee, which identifies chemicals for addition to the Proposition 65 list when they have been "clearly shown, through scientifically valid testing according to generally accepted principles, to cause cancer." Under consideration will be butyl benzyl phthalate, a chemical used in food conveyor belts, and diisononyl phthalate, a plasticizer used in food-contact materials. The meeting will be Webcast. *See OEHHA News Release*, November 14, 2013.

### OEHHA Proposes Listing Rapeseed Oil Emissions as Carcinogenic Under Prop. 65

California EPA's Office of Environmental Health Hazard Assessment (OEHHA) has issued a notice of intent "to list emissions from high-temperature unrefined rapeseed oil as known to the State to cause cancer under the Safe

Drinking Water and Toxic Enforcement Act of 1986" (Prop. 65). The proposal is based on the 2010 cancer identification by the International Agency for Research on Cancer (IARC) for "emissions created by frying food in unrefined rapeseed oil [commonly known as canola oil] heated past its boiling point." IARC apparently found that these emissions "cause increased incidence of malignant tumors in female rats and combined malignant and benign tumors in both sexes of the mouse." Comments are requested by December 16, 2013. *See OEHHA News Release*, November 15, 2013.

## LITIGATION

### Confusion Deemed Likely in Cracker Barrel Infringement Dispute

The Seventh Circuit Court of Appeals has ruled that a district court properly granted Kraft Foods a preliminary injunction against the sale of Cracker Barrel Old Country Store (CBOCS) food products in grocery stores under Kraft's registered trademark name "Cracker Barrel." ***Kraft Foods Group Brands LLC v. Cracker Barrel Old Country Store, Inc.*, No. 13-2559 (7th Cir., decided November 14, 2013)**. The court agreed that consumers could be confused when viewing a CBOCS ham label on a grocery store shelf or in a store circular because the words "Cracker Barrel" were larger than "Old Country Store" and Kraft cheeses also carry the "Cracker Barrel" name. While the logos are not the same, the court said that some consumers might believe that both products were made by Kraft.

The court weighed the respective harms to both companies and found the potential harm to Kraft greater, because it could be wrongly blamed should any of CBOCS's products prove to be inferior to what a consumer expects. On the other hand, CBOCS has other outlets for its meat and deli products, selling them online and through its restaurants' "country stores." According to the court, "irreparable harm is especially likely in a trademark case because of the difficulty of quantifying the likely effect on a brand of a nontrivial period of consumer confusion."

The court further opined, "mainly for future reference," on the consumer survey that Kraft submitted to support its claim of consumer confusion. Noting that the researcher who performed the survey "appears to be basically a professional expert witness," the court described the survey's weaknesses and questioned is "probative significance." Writing for the circuit court panel, Judge Richard Posner also suggested other ways for litigants to prove consumer confusion.

### Putative Class Targets Whole Foods' "All Natural" Food Labels

California residents have filed a putative class action against Whole Foods Market, alleging that the company misleads consumers by labeling certain snack products as "All Natural" because they contain "the synthetic chemical ingredient Sodium Acid Pyrophosphate, among other synthetic ingredients (e.g., Maltodextrin)." *Garrison v. Whole Foods Mkt., Inc.*, No. 13-5222 (U.S. Dist. Ct., N.D. Cal., filed November 8, 2013). Seeking to certify statewide and nationwide classes, the plaintiffs claim that they relied on the truthfulness of the "product label's promise that these Products were 'All Natural,'" paid a price premium over products that are not all natural, "ingested a substance that was other than what was represented," and "ingested a product that did not bring the health benefits Defendant promised."

The products at issue include mini muffins, soft-baked cookies and an array of gluten-free products, including apple pie, cheddar biscuits, corn bread, cookies, and cupcakes. While the plaintiffs mention various claims that the company makes about its products online and in its annual report, they do not contend that they relied on these claims in making their purchasing decisions.

As to the putative California class, the complaint alleges deceptive advertising and unfair business practices under the California Business & Professions Code, violation of the Consumers Legal Remedies Act, and breach of express warranty. As to both putative classes, the complaint alleges common law fraud, negligent misrepresentation, breach of contract, and quasi-contract/unjust enrichment. The plaintiffs seek declaratory and injunctive relief; a corrective advertising campaign; restitution and disgorgement; an accounting and imposition of a constructive trust; compensatory, punitive and exemplary damages; interest; attorney's fees; and costs.

### Frito-Lay to Settle Wage-and-Hour Class Action for $1.6 Million

Subject to court approval, Frito-Lay will pay $1.6 million to settle wage-and-hour claims filed on behalf of current and former employees who deliver its products to stores and arrange the store displays. *Elliott v. Rolling Frito-Lay Sales, LP*, No. 11-1730 (U.S. Dist. Ct., C.D. Cal., filed November 9, 2011). A hearing on the plaintiff's motion for preliminary approval will be held December 23, 2013.

The plaintiff alleged that Frito-Lay did not pay all the wages owed for over-time hours worked, provide duty-free meal periods and rest breaks, provide accurate itemized wage statements, or pay all wages due on cessation of employment to its route sales associates (RSAs), merchandisers and detailers. According to the plaintiff, Frito-Lay calculated overtime pay "using an illegal fluctuating workweek rather than California's mandated forty hours work-week. The effect of utilizing the fluctuating workweek is that the more hours

Plaintiff and RSAs work in excess of forty hours, the lower their overtime rates of pay." The plaintiff also contended that the company's common scheduling policy "deprived Merchandisers and Detailers in practice of the ability to take timely breaks free from work obligations."

While Frito-Lay denies liability, it agreed to establish a settlement that will net an estimated 4,000 employees some $1 million after attorney's fees, costs and enhanced payouts are deducted. Class member claims will be determined using a point system based on a value for each workweek of active employment. Any funds not distributed from valid claims submitted will be provided as an additional award to class claimants. The motion for approval contends that the terms are reasonable, the agreement was reached after extensive discovery and negotiation, and the legal and factual issues raise some uncertainties for both the plaintiff and defendant.

## OTHER DEVELOPMENTS

### *ANZJP* Article Examines Food Addiction in the Context of DSM-5

A recent viewpoint article published in the *Australian & New Zealand Journal of Psychiatry* (*ANZJP*) has raised the question of whether food addiction "is a 'true' and valid addiction, through the lens of the recently released DSM-5," the fifth edition of the American Psychiatric Association's *Diagnostic and Statistical Manual of Mental Disorders*. Nagesh Pai, et al., "Is food addiction a valid phenomenon through the lens of the DSM-5?," *ANZJP,* November 2013. In particular, the article notes that DSM-5 for the first time includes "non-substance related, behavioral or process addictions" such as Gambling Disorder and Internet Gaming Disorder, thus setting the foundation "for the potential future inclusion of food addiction."

"Readers of the DSM-5 that are familiar with the food addiction literature, may be left wondering why food addiction was excluded based upon the rationale for the inclusion of Gambling Disorder," write the article's authors. "Specifically, that gambling activates the same reward and motivation pathways as drugs of abuse."

At the same time, however, the article acknowledges that some researchers "oppose the notion of food addiction being a behavioral or process addiction and instead being comparable to a substance addiction." To this end, the authors examine how food addiction relates to each of the four broad categories of DSM-5's substance use criteria (impaired control, social impairment, risky use, and pharmacological criteria), concluding that "there is compelling evidence for the notion of food addiction as a 'true' addiction."

"From a nosological perspective the phenomenon of food addiction relates to the underlying criteria of addiction espoused in the DSM-5," states the article.

"This is evident in the relationship between food addiction and the concept and rationale for the inclusion of a non-substance use disorder; as well as the diagnostic criteria of substance use disorder. With the change away from considering withdrawal and tolerance as essential features of dependence, food, akin to substances of abuse now meets the ideology of addiction."

### Center for Food Safety Asks FDA for Stronger Protections from Arsenic

In response to the U.S. Food and Drug Administration's request for comments on its "Draft Guidance for Industry on Arsenic in Apple Juice: Action Level," the Center for Food Safety (CFS) has asked the agency to "limit the public's exposure to arsenic through a new regulatory strategy that recognizes the prevalence of arsenic in the food supply." Stating that although individual foods containing arsenic may be safe to eat in moderation, CFS maintains that they are often consumed in combination, thereby presenting a risk of "cumulative arsenic exposure" that could reach dangerous levels. Calling FDA's draft guidance "insufficient" to address these health hazards, CFS's November 12, 2013, **letter** to FDA asks for the agency to regulate based on "cumulative arsenic exposure" rather than through product specific levels.

According to CFS, FDA "must do more" to adequately protect public health. To that end, CFS suggests that, because arsenic is present in a variety of foods and through the environment, FDA act through regulation rather than a nonbinding "action level." The advocacy group also stated that "given arsenic's well-documented prevalence in our food supply, FDA should take into account the multiple sources of arsenic to which consumers may be exposed, and set enforcement standards based on cumulative arsenic exposure accordingly." Lastly, CFS said that "regardless of the means by which FDA sets arsenic standards for apple juice, it should strictly and strongly enforce them."

## MEDIA COVERAGE

### New Catfish Inspection Program Complicates Pacific Trade Agreement

"A curious hurdle is threatening to complicate efforts by the United States to reach a major trade agreement with 11 Pacific nations by the end of the year: catfish," reports *New York Times* writer Ron Nixon in a November 13, 2013, article describing how the U.S. Department of Agriculture's (USDA's) new catfish inspection program has angered Vietnam, a member of the Trans-Pacific Partnership and a major exporter of a catfish known as pangasius. Vietnamese trade officials have apparently written to Secretary of State John Kerry, the White House and Congress, criticizing the new inspection program as a trade barrier in disguise.

FOOD & BEVERAGE LITIGATION UPDATE

ISSUE 504 | NOVEMBER 15, 2013

"And it's not even a good disguise; it's clearly a thinly veiled attempt designed to keep out fish from countries like Vietnam," Le Chi Dzung, the chief economic officer of the Vietnamese Embassy in Washington, D.C., told the *Times*.

Intended to replace the Food and Drug Administration's (FDA's) catfish inspection program, USDA's version is more costly but was backed by consumer groups such as Food and Water Watch as well as lawmakers in Southern states, where domestic catfish producers have long claimed that foreign farmers do not follow the same safety standards required in the United States. "The FDA is understaffed and little inspection is done of the fish that comes into this country," said Consolidated Catfish Co. President and Chief Executive Dick Stevens. "Fish raised in other countries have been found to have drugs in them. We're just saying everyone should be held to the same standard."

The *Times* also notes that USDA recently passed rules requiring all exporters to set up domestic inspection systems that are equivalent to U.S. ones—"an expensive and burdensome regulation that Vietnam says is unnecessary for catfish." In the interim, however, the new USDA catfish program is already under siege in the current farm bill negotiations, with some Congress members holding it up as an example of wasteful government spending and calling for its repeal.

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## FOOD & BEVERAGE LITIGATION UPDATE

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.

SHB 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.

SHB lawyers have served as general counsel for feed, grain, chemical, and fertilizer associations and have testified before state and federal legislative committees on agribusiness issues.