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# WOULD YOU LIKE A PROP 65 WARNING WITH THOSE FRIES?

By

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If the State of California has its way, the next time you order French fries to go with your burger, you will also get a Proposition 65 warning informing you that the fries contain acrylamide, a chemical known to the State of California to cause cancer. The Food and Drug Administration (“FDA”) already has voiced its disapproval of the application of warnings for mercury in canned tuna in a separate Proposition 65 lawsuit filed by the State of California, and the preemption issue may be adjudicated in that case.<sup>1</sup> What, if anything, will the FDA do about Proposition 65 warnings for acrylamide in food, and how will preemption be addressed and resolved in the acrylamide cases?

On August 26, 2005, the State of California filed a lawsuit in Los Angeles County Superior Court against a number of potato chips and French fries manufacturers, as well as fast food restaurants that sell those potato products, asserting that defendants’ potato products expose individuals to acrylamide and that defendants failed to provide “clear and reasonable” warnings.<sup>2</sup> The State also has alleged a derivative claim under the California Unfair Competition Law (the “UCL”), California Business & Professions Code §§ 17200 *et seq.*, asserting that defendants’ violation of Proposition 65 constitutes unfair business practices. The State seeks injunctive relief and civil penalties of up to \$2500 per day under each statute.

The State of California is not alone in prosecuting these acrylamide-in-food cases. Also on August 26, 2005, the Environmental Law Foundation filed Proposition 65 lawsuits against the same defendants as in the State of California action.<sup>3</sup> Another plaintiff, Council for Education and Research on Toxics, filed a

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<sup>1</sup>*People v. Tri-Union Seafoods, et al.*, San Francisco Superior Ct. Case No. GCG-04-432394.

<sup>2</sup>*People v. Frito-Lay, Inc., et al.*, Los Angeles County Superior Ct. Case No. BC338956.

<sup>3</sup>*Environmental Law Foundation v. Procter and Gamble Co.*, Los Angeles County Superior Ct. Case No. BC338895; *Environmental Law Foundation v. Lance, Inc.*, Los Angeles County Superior Ct. Case No. BC338896; *Environmental Law Foundation v. Kettle Foods, Inc.* Los Angeles County Superior Ct. Case No. BC338898; *Environmental Law Foundation v. Frito-Lay (Pepsico, Inc.)*, Los Angeles County Superior Ct. Case No. BC338897.

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similar suit against McDonald's Corporation and Burger King Corporation in 2002.<sup>4</sup> All of the suits are pending in the Los Angeles County Superior Court.

Acrylamide is not found in raw foods, and it is not intentionally added. Rather, it is formed when carbohydrate-rich foods like potatoes are cooked at high temperatures. Concerns about acrylamide in food first arose when Swedish scientists published a study in 2002 demonstrating that acrylamide is found in a wide variety of prepared foods. Since then, acrylamide in food has been the target of focused attention by U.S. and international organizations, like the FDA, seeking to understand the scientific aspects of the issue.

Like the canned tuna case, the issue of federal preemption likely will be adjudicated in the acrylamide cases, and it is possible that the FDA itself may weigh in on the issue pursuant to its authority under Federal Food Drug and Cosmetic Act ("FFDCA") to regulate food labeling and to take action against misbranded foods. 21 U.S.C. § 343(a)(1). How successful the preemption argument will be remains to be seen.

The Nutritional Labeling and Education Act ("NLEA") amendment to the FFDCA contains an express preemption provision, pursuant to which, absent specific federal approval of a state petition,

"no State...may directly or indirectly establish...as to any food in interstate commerce:

(1) any requirement for a food which is the subject of a standard of identity established under section 341 of this title that is not identical to such standard of identity....

(4) any requirement for the nutritional labeling of food that is not identical to the requirement of [the nutritional labeling provisions of the FFDCA at 21 U.S.C. § 343(q)], except a requirement for nutrition labeling of food [which is served for immediate consumption in restaurants or sold for sale or use in restaurants].

21 U.S.C. § 343-1(a).

The FDA, however, has not promulgated a standard of identity for the potato products at issue in the acrylamide cases. Nor has the FDA promulgated any regulation governing acrylamide in food. Thus, the express preemption clause would appear to be inapplicable.

Still, the legislative history of the NLEA indicates that it was not intended to limit the applicability of preemption, express or implied, of state law involving the same subject matter. Pub. L. 101-535, Section 6(c). Thus, a conflict preemption argument, like the one asserted successfully in *Dowhal v. SmithKline Beecham Consumer Healthcare*, 32 Cal.4<sup>th</sup> 910 (2004) (Proposition 65 preempted with respect to warnings on nicotine patches, where FDA issued a letter stating that Proposition 65 warnings on those products may render the products misbranded), may be successful, if, for example, the FDA were to take the position that Proposition 65 warnings for acrylamide in potato products render those foods "misbranded."

The FDA has broad authority to regulate food labeling and the FFDCA prohibits the introduction into interstate commerce of "misbranded" food. 21 U.S.C. § 331(a). The definition of "misbranded" includes labeling that is false or misleading in any particular way, which in turn can include the extent to

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<sup>4</sup>*Council for Education and Research on Toxics v. McDonalds Corp., et al.*, Los Angeles County Superior Ct. Case No. BC280980.

which the labeling fails to reveal material facts with respect to the consequences of eating the food. 21 U.S.C. §§ 343(a)(1), 321(n). A conflict preemption argument may be asserted, then, if the FDA takes the position that potato products bearing Proposition 65 warnings are “misbranded” because those warnings fail to reveal material facts regarding the current uncertainties about the harmful effects, if any, of acrylamide in food, and regarding the amount of food that would have to be eaten to cause any such harm.

The FDA may well take that position. The agency recently has flexed its muscle with the State of California on the issue of Proposition 65 warnings on foods. In the canned tuna Proposition 65 lawsuit by the State of California against sellers of canned and packaged tuna products, the FDA sent California Attorney General Bill Lockyer a strongly worded letter asserting its authority to regulate food labeling:

[T]he agency believes California cannot legally require Proposition 65 warnings on tuna products because they are preempted under federal law, for two principal reasons. First, FDA has been given broad authority to regulate the labels of food products, and has deliberately implemented its regulatory authority with a nuanced approach...and only under exceptional circumstances, requiring manufacturers to provide warnings on their labels.

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Second, the Proposition 65 warnings purport to convey factual information, namely that methylmercury is known to cause cancer and reproductive harm. However, it is done without any scientific basis as to the possible harm caused by the particular foods in question, or as to the amounts of such foods that would be required to cause this harm.

Letter from Commissioner Lester M. Crawford, Commissioner of Food and Drugs to California Attorney General Bill Lockyer, Aug. 12, 2005.

The State of California has punched back, asserting that it has no intention of requiring the Proposition 65 “safe harbor” warning for canned tuna, but rather a more balanced warning, and strongly rejecting the FDA’s preemption argument. Letter from California Attorney General Bill Lockyer to Commissioner Lester M. Crawford, August 30, 2005.

The FDA has not yet formally staked out its position with the State of California on the acrylamide issue as it has on the mercury in canned tuna case. Yet, the same principles articulated in Commissioner Crawford’s letter to the California Attorney General apply in the acrylamide enforcement action. Certainly, to the extent that the FDA has broad authority to regulate labels for canned tuna, the agency also would have broad authority to regulate labels on potato products. Moreover, and as discussed further below, much remains uncertain about the health effects of acrylamide in food. Thus, a Proposition 65 warning for these products would “purport to convey factual information” without, from the FDA’s perspective, adequate scientific foundation. Therefore, it seems likely that the FDA would not approve of warnings on potato products, and would require them only in “exceptional circumstances.”

Those exceptional circumstances do not appear to exist in this situation. The level at which acrylamide actually may cause health effects in humans is the subject of much scientific uncertainty, since existing studies focus on acrylamide exposures at levels much higher than those found in foods. *See* FDA Action Plan for Acrylamide in Food, March 2004 (the “Action Plan”). The FDA, implementing a “nuanced” approach, is examining the issue carefully pursuant to its authority under the FFDCA. *See id.* In collaboration with other agencies, it has conducted, and continues to conduct, studies of prepared foods to ascertain the prevalence of acrylamide in the American food supply. *Id.* The agency is reviewing existing

acrylamide data, including a report released earlier this year from the Food and Agriculture Organization and World Health Organization Joint Expert Commission on Food Additives (“JEFCA”). The FDA also has initiated new toxicology research, with results expected in 2007 and 2008. *See* Action Plan. In short, much remains unknown regarding the prevalence and health effects of acrylamide in food.

The California Office of Environmental Health Hazard Assessment (“OEHHA”), the state agency charged with implementation of Proposition 65, also is carefully considering how acrylamide in food should be regulated under Proposition 65. This year OEHHA proposed three regulatory approaches to the issue: (1) raising the “no significant risk level” for acrylamide from 0.2 micrograms per day to 1.0 microgram per day; (2) an alternative risk level for acrylamide in breads and cereals; and (3) specific warning language for acrylamide in food.<sup>5</sup> The comment period for the proposed rulemakings closed on July 8, 2005, and OEHHA is expected to issue its final regulations later this year.

In the face of all the scientific uncertainty about the actual health effects of acrylamide in food, and federal and state agencies’ efforts to make regulatory sense of the issue, the State of California and other plaintiffs precipitously have pressed on with their Proposition 65 enforcement actions, demanding that warnings be provided for potato chips and French fries. By litigating the issue, these plaintiffs have imposed the burden of resolving complex scientific questions of broad concern to California, the United States, and the world community, onto a limited number of parties and the California judiciary.

The canned tuna case currently is in trial, and the preemption issue may be adjudicated by the court. If the court finds that federal law preempts Proposition 65 in that case, the court in the acrylamide case may well make the same finding, particularly given the apparent absence of the “exceptional circumstances” and the lack of solid scientific data regarding the health effects of acrylamide in food, which FDA would seem to require before requiring warnings on foods. If a preemption challenge is successful, perhaps then California consumers finally can begin to savor the benefits of scientific rigor as applied to the information they get about the foods they eat.

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<sup>5</sup>Notice of Proposed Rulemaking Title 22, California Code of Regulations Amendments to Section 12705b and c, Specific Regulatory Levels Posing No Significant Risk (04/08/05); Notice of Proposed Rulemaking Title 22, California Code of Regulations Amendments to Section 12705e, Specific Regulatory Levels Posing No Significant Risk: Acrylamide (04/08/05); Notice of Proposed Rulemaking Title 22, California Code of Regulations Amendments to Section 12601, Clear and Reasonable Warning: Acrylamide (04/08/05).