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State of California
DEPARTMENT OF JUSTICE

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July 9, 2002

Raphael Metzger
Law Offices of Raphael Metzger
401 East Ocean Boulevard, Suite 800
Long Beach, CA 90802-4966

RE: Council for Education and Research on Toxics
Proposition 65 Notices re Acrylamide

Dear Mr. Metzger:

We have received the sixty-day notices of violation under Proposition 65 sent on behalf of your client, the Council for Education and Research on Toxics ("CERT"), alleging that McDonald's and Burger King have exposed consumers to french fries containing acrylamide, without first providing a clear and reasonable warning. According to the certificate of service, the notices were mailed on May 1, 2002. Since the addresses at which the alleged violators were served are outside the State of California, ten days must be added to the time before which a suit under Proposition 65 could be filed. (22 CCR § 12903(d)(1).) Thus, the first date on which a complaint could be filed is July 10, 2002.[1]

Additionally, recent publicity concerning the presence of acrylamide in certain cooked foods raises an issue of substantial public importance, which deserves serious attention. The World Health Organization, the U.S. Food and Drug Administration, and others, are investigating this matter. The Attorney General also is investigating the matter. Accordingly, we are writing in order to express some of our concerns about this issue.

A. Publicly Available Information on Acrylamide

[1]In addition, we have received sixty-day notices from Environmental World Watch alleging that Frito-Lay, Inc., Wendy's International, Inc., General Mills, Inc., H.J. Heinz Company, Procter & Gamble Company, and KFC of America, Inc., have failed to warn of acrylamide exposures. These notices, however, did not include a certificate of merit or supporting factual information required by Health and Safety Code section 25249.7(d)(1), and, accordingly, do not permit Environmental World Watch to sue under Proposition 65.

On April 24, 2002, Stockholm University and the Swedish National Food Administration announced that test results on over 100 samples of bread, biscuits, potato chips and french fries contained high levels of acrylamide. The information released summarizes these test results, indicating that potato "crisps" contained a median of 1200 parts per billion acrylamide, french fries a median of 450, with other products containing lower levels, e.g., soft breads 40 ppb. The Swedish NFA's website contains a summary description of the results, discussing the ramifications of the findings, generally describing the results, and generally discussing the analytical testing methodology. The study found no acrylamide in the raw ingredients of the tested products, and suggests that it is "formed in many types of food prepared/cooked at high temperatures." (NFA website, http://192.71.90.8/engakrylrekommendationer.htm.)

Although a Reuters news item states that the french fries tested were from Swedish franchises of Burger King and McDonald's, we found no discussion in the material released by the NFA of the sources of the samples.

Finally, we note that the NFA study has not been published in any peer-reviewed literature, nor are we aware of any release of the actual analytical data, quality control/quality assurance data, or any other validating information.

In commenting on the limitations of the currently available information, however, we recognize that the findings of the study raise a very serious issue that must be reviewed, and is in fact being reviewed intensively by a number of organization.

B. Certificate of Merit Requirements

Notices alleging violations of the warning requirement must include a "certificate of merit," which shall state

> that the person executing the certificate has consulted with one or more persons with relevant and appropriate experience or expertise who has reviewed facts, studies, or other data regarding the exposure to the listed chemical that is the subject of the action, and that, based on that information, the person executing the certificate believes there is a reasonable and meritorious case for the private action. Factual information sufficient to establish the basis of the certificate of merit...shall be attached to the certificate of merit that is served on the Attorney General.

(Health and Safety Code § 25249.7(d)(1).) The supporting information is deemed "confidential

official information to the full extent authorized in Section 1040 of the Evidence Code."[2] In the event that CERT files a case, and the court ultimately concludes that there was not actual or threatened exposure to a listed chemical, the court may review the information, and if there was "no credible factual basis for the certifier's belief that an exposure occurred or was threatened," the action is deemed frivolous, and the plaintiff is subject to sanctions.

Each notice includes a Certificate of Merit. In those Certificates, you state that "Recent medical studies have concluded that [Burger King's/McDonald's] french fries contain approximately 100 times more acrylamide than the maximum level permitted by the World Health Organization for drinking water." (Certificate of Merit, p. 4.)

C. No Significant Risk Regulations

Regulations implementing Proposition 65 provide methods and standards for determining whether exposure to a listed carcinogen poses "no significant risk" of cancer, and therefore does not require a warning. (See 22 CCR §§ 12701-12721.) Current regulations set the No Significant Risk Levels for listed carcinogens, based on OEHHA's determination of the amount that "is calculated to result in one excess case of cancer in an exposed population of 100,000, assuming lifetime exposure at the level in question." (22 CCR § 12703(b).) For acrylamide, OEHHA has determined that the No Significant Risk Level is 0.2 micrograms per day. (22 CCR § 12705(c)(2.)

The regulations also provide, however, that the 1 in 100,000 risk level does not apply "where sound considerations of public health support an alternative level, as, for example: (1) where chemicals in food are produced by cooking necessary to render the food palatable or to avoid microbiological contamination[.]"[3] The Final Statement of Reasons issued by the lead agency in adopting this regulation sheds additional light on the full scope and meaning of the provision.[4] As the agency noted:

The public health benefits of cooking food are widely recognized. Cooking food

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[2]The factual information discussed in this letter is taken entirely from publicly available sources.

[3]The other examples provided are chlorine disinfection and government-supervised site clean-ups. (22 CCR § 17203(b)(2),(3).)

[4]At the time the regulation was adopted, the lead agency was the Health and Welfare Agency. It is now the Office of Environmental Health Hazard Assessment.

> significantly minimizes the possibility of food-borne infections and food intoxication. The high temperatures that foods are subject to during cooking are effective in killing pathogenic bacteria, helminths and other organisms[.] ... In addition to its anti-microbial benefits, cooking is often necessary to make foods palatable. Experience has shown that, when food isn't palatable, people tend not to eat. This can have health consequences as well.

(Statement of Reasons, at 4; copy attached.) The agency noted that a number of chemicals listed as carcinogens are by-products of the cooking process, and vary depending on the cooking method, temperature, and duration. (*Id.*) It went on to state:

> The confusion which would result if all purveyors of cooked or heat-processed foods provide a warning with their product, to avoid any potential liability, could be enormous. If the warning were to specify that it is given for cooking, it could generate undue public fear about cooking food, leading some to undercook their food or avoid cooking altogether. This could result in an increase in the transmission of food-borne diseases. If the warning does not specify that it is given for cooking, consumers might avoid foods carrying the warning in favor of raw foods, which more likely would not carry a warning. Since most consumers cook raw food, they would expose themselves to the same listed chemicals anyway. Thus, consumers are likely to be exposed to these chemical by-products of cooking in any event. In light of the offsetting public health benefit that the cooking of food provides, the Agency takes the position that businesses which utilize cooking necessary for the processing or preparation of food should not be strictly held to the 10-5 standard.

(*Id.*) The summary results of the NFA study indicated that acrylamide did not appear in boiled foods, and thus frying or grilling arguably is not "necessary" to cook at least some of the foods in question. The agency addressed this issue by stating:

> The word "necessary" in not intended to favor one cooking practice over another. If a food could be boiled or broiled to avoid contamination or render the food palatable, but broiling produces more chemical by-products than boiling, broiling does not become unnecessary. The Agency's intention is that, whatever method of cooking is chosen, the amount of cooking which is necessary to avoid bacterial contamination or to render the food palatable should provide a basis for the application of a risk level other than a risk of 1 x 10-5.

(*Id.*, at 6-7.) The agency also noted that "[t]he word 'palatable' means 'acceptable to the taste; sufficiently agreeable in flavor to be eaten'," and that this refers to "the taste of an ordinary

person." (*Id.*) Finally, the agency acknowledged that in some instances, factual issues will exist as to whether certain cooking was necessary to avoid contamination or render the food palatable. (*Id.*)

D. Conclusions

The issues raised by the Swedish NFA study are quite serious, and will be the subject of substantial investigation by a number of entities, going beyond the confines of Proposition 65.

With respect to these particular notices alleging violations of Proposition 65 however, and without commenting on or disclosing the actual supporting information submitted in support of your Certificate of Merit, we do not think that you have provided "factual information sufficient to establish the basis of the certificate of merit" as required by Health and Safety Code section 25249.7(d)(2). Although the statute does not grant the Attorney General authority to preclude a party from filing suit based our determination, we think you should consider this determination in deciding whether to file a civil action based on your notice. We do not suggest that it will never be possible to craft a sufficient certificate of merit for similar allegations, but we do not think this particular certificate is adequate with respect to the specific allegations of the notice. Of course, because of the importance of this matter, our consideration will not be limited to the violations alleged in your notices, but will continue on a broader scale.

In addition, if it is shown that acrylamide is a by-product of cooking, then the alleged violation in your notices may fall within the scope of the alternative risk level provisions of section 12703 of the regulations. To the extent that the level of acrylamide present is a result of "necessary" cooking falling within that provision, then it would be subject to an alternative significant risk level. While the burden of establishing the applicability of this provision would be on the defendants in a civil action, we presume that the Center for Education and Research on Toxics is not interested in filing a complaint merely in order to put the defendants to their burden of proof, or in order to use the litigation process to force warnings that may not be required by the law. Given the limited publicly available information at this time, Proposition 65 litigation against large numbers of food processors or sellers may not be appropriate or in the public interest. In fact, as you authorized me to state in this letter, you agree that the provision of sixty-day notices and filing of complaints against the vast numbers of retailers and providers of these food products in California would not be the best way to promote the public health at this time. Once further information concerning the nature and extent of the exposure is available, all concerned will be in a better position to evaluate whether action under Proposition 65, or other laws, is the way to protect the public health.

Of course, the Office of the Attorney General will continue to evaluate this issue as more scientific information is developed. Please contact me if you would like to discuss this matter.

Sincerely,

EDWARD G. WEIL
Deputy Attorney General

For BILL LOCKYER
Attorney General

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Dear Mr. Metzger

In our letter of July 9, 2002, at footnote 1, we stated that the sixty-day notices of violation provided by Environmental World Watch did not include Certificates of Merit as required by SB 471. This statement was incorrect, and was made due to an error on our part.

Sincerely,

EDWARD G. WEIL
Deputy Attorney General

For BILL LOCKYER
Attorney General

cc: Robert Mandell