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July 20, 2004

OCCUPATIONAL & ENVIRONMENTAL LUNG
DISEASE, CANCER, AND TOXIC INJURIES

The Honorable Arnold Schwarzenegger
Governor of the State of California
State Capitol
Sacramento, CA 95814

Re: Acrylamide in High-Temperature Fried Potato Products
& the Safe Drinking Water and Toxic Enforcement Act
(commonly known as Proposition 65)

Dear Governor Schwarzenegger:

This letter is written in response to the letter addressed to you by the Agricultural Council of California and other members of the agricultural and food industries, to explain the necessity and importance to the health of Californians of anticipated regulatory action by the Office of Environmental Health Hazard Assessment of the California Environmental Protection Agency concerning acrylamide in high-temperature fried potato products.

The Cancer Epidemic and Carcinogens in the Human Diet

More than four out of every ten Californians suffer from cancer. California, along with the rest of the nation, is therefore facing an epidemic of staggering proportions, affecting the health of almost half the population, with attendant pain, suffering, death, loss of productivity and huge health care costs.

Almost all public health experts have concluded that occupational exposure to industrial carcinogens and environmental pollution account for only a small percent of human cancer, and that most human cancer is due to the human diet. However, until Swedish researchers detected high levels of acrylamide in french fries and other high-temperature fried potato products two years ago, no carcinogen had been known to constitute a major part of the human diet. Acrylamide, an industrial carcinogen (as well as a potent neurotoxin) has now been determined to constitute a substantial part of the human diet, especially from high-temperature cooked potato products such as french fries and potato chips. Thus, the presence of acrylamide in fried potato products is a substantial issue of concern to Californians. Indeed, some consider it to be the most important health issue of the century.

Acrylamide and Cancer

Acrylamide is an industrial chemical used in water treatment, oil drilling, pulp and paper, mineral processing, biotechnology, and other industries.¹ Acrylamide is not known to occur as a natural product.²

Acrylamide is recognized as a neurotoxin in animals and in humans.³ In experiments exposing animals to acrylamide, reproductive toxicity (damage to testicles and sperm) has been reported; the genotoxicity of acrylamide has been studied extensively and is well established.⁴

In 1994 the International Agency for Research on Cancer (IARC) of the World Health Organization (WHO) reviewed the studies that were then available regarding the carcinogenicity of acrylamide and concluded at the time that "acrylamide is *probably carcinogenic to humans.*"⁵

Also in 1994, the U.S. Department of Health and Human Services (DHHS), the Public Health Service (PHS), and the National Toxicology Program (NTP) determined that acrylamide is "*reasonably anticipated to be a human carcinogen.*"⁶

In the decade since the international community and the U.S. government recognized that acrylamide is probably carcinogenic to humans, additional studies have been published which provide further evidence of acrylamide's carcinogenicity to humans.

¹ International Agency for Research on Cancer, "Acrylamide," IARC Monographs on the Evaluation of Carcinogenic Risks to Man 60:389-433 at p. 391-395 (1994).

² IARC (1994) at p. 392.

³ Institute for Health and Consumer Protection, Europeans Chemicals Bureau, Joint Research Centre, European Commission. Acrylamide: Summary Risk Assessment Report (2001).

⁴ IARC (1994) at p. 424-425.

⁵ IARC (1994) at p. 425.

⁶ U.S. Department of Health and Human Services, the Public Health Service, and the National Toxicology Program, "Acrylamide," Report on Carcinogens (10th ed. 2002).

First, in 1999, a followup epidemiologic study of acrylamide production workers was published. This study reported a statistically significant 2.25-fold increase in pancreatic cancer among workers with cumulative exposure to acrylamide greater than 0.3 mg/m³ years.⁷ A further analysis of the data from this study showed a dose-response relationship among the acrylamide workers.⁸

These findings are important for several reasons. First, the type of cancer found to be in excess among the exposed workers was pancreatic cancer, which indicates that acrylamide is likely a digestive tract carcinogen. Because the type of cancer found to be in excess was a cancer of the digestive tract (rather than a cancer in some other organ system), the carcinogenic hazard of acrylamide is directly relevant to consumer ingestion of high-temperature cooked potato products. Second, because the excess of pancreatic cancer found among the exposed workers was statistically significant, there is less than a 5% chance that the cancer excess was due to chance. Finally, there is a strong likelihood that the excess of pancreatic cancer among the exposed workers was due to acrylamide (rather than some other factor), because further analysis of the data showed that the pancreatic cancer excess among the exposed workers increased as the workers' exposure to acrylamide increased.

The results of the acrylamide production worker studies provides epidemiologic evidence of the carcinogenicity of acrylamide to humans which was lacking at the time of IARC's evaluation of the carcinogenicity of acrylamide which was published in 1994. At the time IARC concluded that acrylamide was probably carcinogenic to humans, it based its conclusion on data showing that acrylamide is carcinogenic to experimental animals and other supporting data. Specifically, IARC took into consideration the following supporting evidence:

- (i) Acrylamide and its metabolite glycidamide form covalent adducts with DNA in mice and rats.
- (ii) Acrylamide and glycidamide form covalent adducts with haemoglobin in exposed humans and rats.

⁷ Marsh, G. M., et al., "Mortality patterns among workers exposed to acrylamide: 1994 follow up," Occup. Environ. Med. 67:181-190 (1999).

⁸ Schulz, M.R., et al., "Dose-response relation between acrylamide and pancreatic cancer," Occup. Environ. Med. 58:609 (2001).

(iii) Acrylamide induces gene mutations and chromosomal aberrations in germ cells of mice and chromosomal aberrations in germ cells of rats and forms covalent adducts with protamines in germ cells of mice *in vivo*.

(iv) Acrylamide induces chromosomal aberrations in somatic cells of rodents *in vivo*.

(v) Acrylamide induces gene mutations and chromosomal aberrations in cultured cells *in vitro*.

(vi) Acrylamide induces cell transformation in mouse cell lines.⁹

All of this evidence shows that acrylamide damages chromosomes and genetic material. IARC considered this evidence relevant to human cancer, because the types of genetic damage caused by acrylamide (DNA adducts, hemoglobin adducts, germ cell mutations, and chromosome aberrations) are those which are involved in the early stages of carcinogenesis.

In the decade since IARC evaluated the carcinogenicity of acrylamide, several additional studies reporting genotoxic effects of acrylamide have been published, which provide further support for the human carcinogenicity of acrylamide.¹⁰

⁹ IARC (1994) at p. 425.

¹⁰ See, e.g., Abramson-Zetterberg, L., "The Dose-Response Relationship at Very Low Doses of Acrylamide Is Linear in the Flow Cytometer-based Mouse Micronucleus Assay," Mutat. Res. 535(2):215-222 (2003); Barber, D.S., et al., "Metabolism, toxicokinetics and hemoglobin adduct formation in rats following subacute and subchronic acrylamide dosing," Neurotoxicol. 22(3):341-53 (2001); Bergmark, E., "Hemoglobin adducts of acrylamide and acrylonitrile in laboratory workers, smokers and nonsmokers," Chem. Res. Toxicol. 10(1):78-84 (1997); Besaratinia, A., et al., "Weak yet distinct mutagenicity of acrylamide in mammalian cells," J. Natl. Cancer Inst. 95(12):889-896 (2003); Gamboa De Costa, "DNA Adduct Formation From Acrylamide via Conversion to Glycidamide in Adult and Neonatal Mice," Chem. Res. Toxicol. 16:1328-1337 (2003); Paulsson B., et al., "Induction of micronuclei in mouse and rat by glycidamide, genotoxic metabolite of acrylamide," Mutat. Res. 535(1):15-24 (2003); Paulsson, B., et al., "Hemoglobin adducts and micronucleus frequencies in mouse and rat after acrylamide or N-methylolacrylamide treatment," Mutat. Res. 516(1-2):101-111 (2002).

Regulation of Acrylamide Exposure

Pursuant to the Safe Drinking Water Act of 1974, the EPA is required to determine safe levels of toxic chemicals in drinking water. The EPA has set a Maximum Contaminant Level Goal (MCLG) for acrylamide of zero.¹¹ To meet that goal, the EPA requires water suppliers to show that "when acrylamide is added to water, the amount of uncoagulated acrylamide is less than 0.5 ppb."¹²

In June 2002, the FDA issued a final food additive regulation providing for the safe use of acrylamide-acrylic acid resins ("AAR"). The FDA determined that AAR may contain acrylamide, which the FDA noted "is a recognized neurotoxin."¹³ However, the FDA approved AAR as a food additive, because it estimated that daily exposure to acrylamide from AAR would be less than 2 nanograms per person - much less than the 12 micrograms per person that the FDA determined was the safe daily level. Id.

In 1990 the California Environmental Protection Agency (Cal-EPA) established a No Significant Risk Level (NSRL) for acrylamide of 0.2 micrograms/day.¹⁴

Proposition 65

In 1986, Californians expressed their concern regarding unwitting exposure to carcinogens by voting by a two-thirds majority to adopt Proposition 65 - the Safe Drinking Water and Toxic Enforcement Act. The premise of Proposition 65 is simple. It imposes no restrictions on the sale of products which cause cancer in California. It simply requires companies who expose Californians to cancer-causing substances to warn Californians of the fact so that concerned Californians can make informed lifestyle choices. Since most companies generally consider a cancer hazard warning to be a marketing detriment, affected companies have generally attempted to reformulate their products to remove carcinogenic components from them in lieu of providing cancer hazard warnings. The law has resulted in decreased exposure of Californians to carcinogens - without coercion or loss of business.

¹¹ 40 C.F.R. § 141.50(a) (2002).

¹² EPA, "Consumer Factsheet on Acrylamide"

¹³ 67 F.R. 42715 (June 25, 2002)

¹⁴ 22 C.F.R. § 12705(c)

The Current Controversy

When it became apparent that millions of Californians were daily being exposed to dangerous levels of acrylamide in french fries and other high-temperature cooked potato products, the Council for Education and Research on Toxics (CERT), a California public benefit organization devoted to education and research on toxic chemicals, requested my firm to prepare a notice to McDonald's and Burger King, advising them that they were exposing millions of Californians to dangerous levels of acrylamide in french fries without warning Californians thereof. On behalf of CERT my firm prepared the legal notices, requesting McDonald's and Burger King to give Californians the cancer hazard warnings required by law. We purposefully did not give the notice to other fast food companies, because we felt that if McDonald's and Burger King, as the leaders in the fast food industry (and good corporate citizens) complied with the law, the rest of the industry would follow suit without the necessity of incurring litigation expense.

OEHHA'S Re-Evaluation of Acrylamide Carcinogenicity

In light of the new scientific findings, OEHHA has re-evaluated the carcinogenicity and human health risk of acrylamide. Its re-evaluation has confirmed the carcinogenicity of acrylamide and that a few products--especially french fries and potato chips--present a substantial cancer risk to Californians. Accordingly, OEHHA is in the process of issuing a "safe-harbor warning" which will have to be given for a few "high risk" products to comply with Proposition 65.

The Food Industry's Request for Your Intervention

It is in anticipation of OEHHA's findings that many members of the food industry have written, asking you to intervene on their behalf. However, gubernatorial intervention in the regulatory process is unnecessary and would be unwise for the following two reasons:

First, OEHHA's regulatory action will likely require cancer hazard warnings for only a few consumer products that contain extremely high levels of acrylamide, i.e., french fries and potato chips. Accordingly, only a small segment of the food industry (french fries and potato chips) should be affected and there will be no generalized food scare or hysteria; California agriculture and the food industry will generally not be affected.

Second, during the past two years, much research has been done on the formation of acrylamide in french fries and potato chips and scientists have now devised improved food processing and cooking systems which can substantially reduce acrylamide in cooked foods -- even french fries and potato chips -- without affecting taste or marketability. Indeed, a new study recently published by the Food Control Authority in Zurich, Switzerland concludes: "With ... improved methods of preparation ..., a massive reduction of acrylamide concentrations can be achieved." ¹⁵

Since the impact of OEHHA's regulations will likely affect only a few of the worst offending (most carcinogenic) products and since the technology and knowledge now exist for the fast food industry to adopt alternative food processing methods which can reduce the acrylamide concentration of french fries and potato chips to the low levels found in other foodstuffs, we believe that the regulatory process should be allowed to proceed without precipitous gubernatorial intervention on behalf of the agricultural and food industries, whose concerns are clearly overstated.

Summary and Conclusion

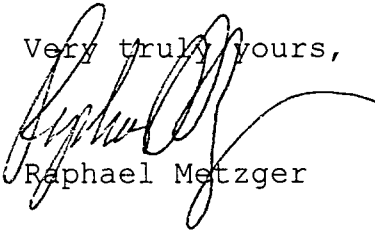
Californians have the right to know if food they eat causes cancer. This right is both a moral right and a legal right which the People of the State of California granted themselves by public referendum in 1986. OEHHA's cancer hazard warnings for acrylamide-containing foods will likely apply to only a few products, e.g., french fries and potato chips, whose manufacturers can either use available alternative food processing technologies to reduce the level of acrylamide in their products to levels found in other foods, or, should they decline to do so, give the cancer hazard warnings required by law. OEHHA's new regulations should be focused only on the few "bad actors" that present the greatest risk of cancer to Californians from acrylamide. The targeted approach of OEHHA and public interest organizations such as CERT will assure that Californians receive the cancer hazard warnings to which they are entitled for the few "bad actor" products, without negatively impacting California agriculture, the food industry, or commerce. We therefore urge you not to succumb to the hysterical overtures of the agricultural and food industries, and to allow the regulatory process to proceed without unnecessary gubernatorial intervention.

¹⁵ Biedermann, M., et al., "Methods for Determining the Potential of Acrylamide Formation and Its Elimination in Raw Materials for Food Preparation, such as Potatoes," Mitteilungen aus Lebensmitteluntersuchung und Hygiene (2004) (in press).

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Please feel free to contact my firm if you have any concerns or questions regarding this important public health issue.

Very truly yours,

A handwritten signature in black ink, appearing to read 'Raphael Metzger', with a long, sweeping flourish extending to the right.

Raphael Metzger

RM:ip
cc: Joan Denton, OEHHA