FILE COPY

Metzger Law Group

Practice Concentrated in Toxic Tort & Environmental Litigation

401 E Ocean Blvd, Ste 800
Long Beach, CA 90802
phone: 562.437.4499
fax: 562.436.1561

www.toxictorts.com

Attorneys
Raphael Metzger
Greg Coolidge
Monica L. Frye

Administrator
Robert Hann

April 29, 2005

Ms. Cynthia Oshital
Office of Environmental Health Hazard Assessment
P.O. Box 41010
Sacramento, CA 95812-4010

Re: Public Workshop May 9, 2005

Dear Ms. Oshita:

Enclosed is the brief of Council for Education and Research on Toxics (CERT) in Opposition to Proposed Regulation Exempting From the Proposition 65 Warning Requirements Exposures From Chemicals That Form From Natural Constituents in Food During Cooking or Heat Processing.

Very truly yours,

Virginia Flyn

Raphael Metzger

RM:vf
Enclosure

F:\WP\CASES\5528\CORRESP\OEHHA\2005-04-29.ltr.wpd

BEFORE THE

CALIFORNIA ENVIRONMENTAL PROTECTION AGENCY

OFFICE OF ENVIRONMENTAL HEALTH HAZARD ASSESSMENT

BRIEF OF

COUNCIL FOR EDUCATION AND RESEARCH ON TOXICS (CERT), A CALIFORNIA PUBLIC BENEFIT CORPORATION

IN OPPOSITION TO PROPOSED REGULATION EXEMPTING FROM THE PROPOSITION 65 WARNING REQUIREMENTS EXPOSURES FROM CHEMICALS THAT FORM FROM NATURAL CONSTITUENTS IN FOOD DURING COOKING OR HEAT PROCESSING

HEARING DATE: MAY 9, 2005

Metzger Law Group
Raphael Metzger, Esq.
Monica Frye, Esq.
401 E. Ocean Blvd., Suite 800
Long Beach, CA 90802

Attorneys for
Council for Education and Research on Toxics
A California Public Benefit Corporation

TABLE OF CONTENTS

Page

I STATEMENT OF CONCERN AND INTEREST 1

II SUMMARY OF POSITION 1

III THE PROBLEM OF ACRYLAMIDE CARCINOGENICITY FROM FRENCH FRIES 2

IV HOW COMMERCIAL FRENCH FRIES ARE MADE 6

V THE PROPOSED REGULATION WOULD THWART THE WILL OF THE PEOPLE 10

VI IF OEHHA ADOPTS AN EXEMPTION FOR ACRYLAMIDE FROM COOKING, IT SHOULD NOT APPLY TO ACRYLAMIDE RESULTING FROM FOOD PROCESSING 12

VII IF OEHHA ADOPTS AN EXEMPTION FOR ACRYLAMIDE FROM COOKING, THE EXEMPTION SHOULD ONLY APPLY WHERE THE CONCENTRATION OF ACRYLAMIDE IS REDUCED TO THE LOWEST LEVEL ACHIEVABLE BY APPLICATION OF STATE OF ART KNOWLEDGE AND TECHNOLOGY 13

VIII CONCLUSION 14

TABLE OF AUTHORITIES

Page(s)

Cases

California Teachers Association v. California Commission on Teacher Credentialing (2003) 111 Cal.App.4th 1001 11

City of San Jose v. Department of Health Services (1998) 66 Cal.App.4th 35 11

Statutes

Gov. Code § 11342.2 11

Proposition 65 . . . . . 1,10, 11,12,14

Regulations

21 C.F.R. § 173.315 9

Articles

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) 5

Amrein, T.M., et al., "Potential of acrylamide formation, sugars, and free asparagine in potatoes: a comparison of cultivars and farming systems," *J. Agric. Food Chem.* 51(18):5556-5560 (2003) 13-14

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) 5

Bergmark, E., "Hemoglobin adducts of acrylamide and acrylonitrile in laboratory workers, smokers and nonsmokers," Chem. Res. Toxicol. 10(1):78-84 (1997) 5

Besaratinia, A., et al., "Weak yet distinct mutagenicity of acrylamide in mammalian cells," J. Natl. Cancer Inst. 95(12):889-896 (2003) 5

Biedermann, M., et al., "Experiments on Acrylamide Formation and Possibilities to Decrease the Potential of Acyrlamide Formation in Potatoes," *Mitteilungen aus Lebensmitteluntersuchung und Hygiene,"* in press (2004) 13

"How Commercial French Fries Are Made," Official French Fry Page, formerly located at http://www.tx7.com/fries/docs/production.html, but still accessible at http://web.archive.org/web/20011114140726/http://www.tx7.com/fries/docs/production.html . . 6

TABLE OF AUTHORITIES

Page(s)

Articles - continued

Gamboa De Costa, "DNA Adduct Formation From Acrylamide via Conversion to Glycidamide in Adult and Neonatal Mice," Chem. Res. Toxicol. 16:1328-1337 (2003) 5

Institute for Health and Consumer Protection, Europeans Chemicals Bureau, Joint Research Centre, European Commission. Acrylamide: Summary Risk Assessment Report (2001) 2

International Agency for Research on Cancer, "Acrylamide," IARC Monographs on the Evaluation of Carcinogenic Risks to Man 60:389-433 (1994) 2,3,4

Marsh, G. M., et al., "Mortality patterns among workers exposed to acrylamide: 1994 follow up," Occup. Environ. Med. 67:181-190 (1999) 3

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) 5

Paulsson B., et al., "Induction of micronuclei in mouse and rat by glycidamide, genotoxic metabolite of acrylamide," Mutat. Res. 535(1):15-24 (2003) 5

Schulz, M.R., et al., "Dose-response relation between acrylamide and pancreatic cancer," Occup. Environ. Med. 58:609 (2001) 3

U.S. Department of Health and Human Services, the Public Health Service, and the National Toxicology Program, "Acrylamide," Report on Carcinogens (10th ed. 2002) 3

"Why the Fries Taste Good" in Eric Schlosser's Fast Food Nation, pgs. 111-131 6

World Health Organization, "Cancer: Diet and Physical Activity's Impact," http://www.who.int/dietphysicalactivity/publications/facts/cancer/en/print.html 5

Taubert, D., et al., "Influence of processing parameters on acrylamide formation during frying of potatoes," *J. Agric. Food Chem.* 52(9):~~2735~~-2739 (2004) 14

I

STATEMENT OF CONCERN AND INTEREST

The Council for Education and Research on Toxics (CERT) is a California public benefit corporation whose charitable purposes include education and research regarding toxic substances. Since researchers in Sweden reported high levels of acrylamide in French Fries and certain other foodstuffs three years ago, CERT has been concerned that the presence of high levels of this industrial carcinogen in the human diet could account for much of the dietary burden of human cancer.

Due to its concern that acrylamide in fried foods could be responsible for a large percentage of cancers from which Californians suffer, CERT provided notices of violations of Proposition 65 to McDonald's and Burger King in mid- 1992. When these fast food corporations refused to provide Californians with cancer hazard warnings required by Proposition 65, CERT filed a private enforcement action against them to secure their compliance with the law. CERT's enforcement action was stayed by the Superior Court pending OEHHA's action on the acrylamide issue. Thus, CERT is clearly a genuinely concerned and interested party in OEHHA's acrylamide determinations.

II

SUMMARY OF POSITION

CERT believes there should be no exemption for exposures from chemicals that form from natural constituents in food during cooking or heat processing, because Proposition 65 expressed the will of the People that they be informed of carcinogens to which they are exposed so that they can make their own informed decisions of carcinogenic hazards and risks to their health. However, if OEHHA nevertheless decides to adopt an exemption for acrylamide from cooking, the exemption

should be clarified to provide that acrylamide which is produced as a result of food processing other than cooking or heating is not exempted and that the exemption will only apply where application of state of art technology in cooking and food preparation is used to reduce acrylamide to the lowest level that can be achieved by modern science (as opposed to mere "good cooking and manufacturing processes"). Otherwise, the exemption would allow the food industry, without providing cancer hazard warnings, to unnecessarily expose Californians to high levels of acrylamide in foods even though the technology exists to greatly reduce the acrylamide content of the foods. An exemption should not license manufacturers to expose Californians to unnecessarily high levels of acrylamide.

III

THE PROBLEM OF ACRYLAMIDE CARCINOGENICITY FROM FRENCH FRIES

It is generally known that French Fries are not good for one's health, because they contain high levels of saturated fat and cholesterol, which cause obesity and heart disease. However, until three years ago, it was not known by the medical community that French Fries contain high levels of acrylamide and might thus be responsible for a substantial percentage of cancer in consumers.

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

---

[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).

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.

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/m^3 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 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

---

[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).

[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).

acrylamide is directly relevant to consumer ingestion of french fries. 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.

(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.

---

[9] IARC (1994) at p. 425.

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]

According to the World Health Organization, cancer accounts for 7.1 million deaths annually and dietary factors account for about 30% of all cancers in Western countries.[11] Apart from acrylamide, the known carcinogens in the human diet are heterocyclic amines, polycyclic aromatic hydrocarbons, and aflatoxin. However, aflatoxin is rare in the human diet, generally being present as the result of unsanitary food preparation, and heterocyclic amines and polycyclic aromatic hydrocarbons typically are only present in the human diet as a result of overcooking meat. In any event, to the extent that these carcinogens are present in the human diet, they constitute only a small percentage of the dietary carcinogenic load. Mounting evidence indicates that acrylamide is the major carcinogen in the human diet and that it may well account for as much as 25% of the dietary carcinogenic load in Western countries. If acrylamide comprises just one-tenth of the dietary

---

[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).

[11] World Health Organization, "Cancer: Diet and Physical Activity's Impact," http://www.who.int/dietphysicalactivity/publications/facts/cancer/en/print.html.

carcinogenic load, it may be responsible for as many as 250,000 deaths annually. Given the high levels of acrylamide in french fries and their widespread high-volume consumption, a conservative estimate of the toll of acrylamide from french fries would be 100,000 cancer deaths annually. Thus, acrylamide from french fries should be considered a major cancer hazard to the consuming public.

IV

HOW COMMERCIAL FRENCH FRIES ARE MADE

Based upon information that has been published on the Internet,[12] following is an overview of the commercial processes by which potatoes are made into french fries:

Step 1: Obtain and inspect potatoes. Potatoes are checked for solids content (solids v. water content), quality grade, and sugar content. Potato sugar content is naturally less in the fall than it is in the spring. The most commonly used potato varieties are Russet Burbank or Idaho Russett, Ranger Russett, Norkota, and Shepody. Every year, more than 2.2 million metric tons of potatoes, or approximately 49% of total United States potato production, become french fries. These potatoes come either directly from producers (i.e. farms) or large warehouses, depending on the location of the processing plant and the time of year.

Step 2: Washing potatoes. These potatoes are then dumped into a rock trap, a tank of water in which the potatoes are floated and rocks fall to the bottom. Water sorting systems are used to float the potatoes, guiding different sizes into different holding bays, then flushing them into a three-foot-deep stream that runs beneath the cement floor into the interior of the processing plant.

Step 3: Peeling potatoes. Conveyor belts take the wet, clean potatoes into a large,

---

[12] "Why the Fries Taste Good" in Eric Schlosser's Fast Food Nation, pgs. 111-131; "How Commercial French Fries Are Made," Official French Fry Page, formerly located at http://www.tx7.com/fries/docs/production.html, but still accessible at http://web.archive.org/web/20011114140726/http://www.tx7.com/fries/docs/production.html.

pressurized and heated tank that blasts the potatoes with steam for twelve seconds, boiling the water underneath their skins. The steam created by this process, flays off the potato skins. The potatoes are then sprayed with high-power jets to remove any remaining skins. The removed peelings are either processed as cattle feed or run through a system which lets them decompose and uses the resulting methane to offset the energy needs of the plant.

Step 4: Inspection (#1). The potatoes are run past an inspection line where sorters, both mechanical and human, remove any potato which looks defective (i.e., rot or aesthetic abnormalities). The rejected potatoes are taken away and mascerated and the resulting potato starch is used in things like chemical glues and papermaking.

Step 5: Cutting potatoes. The potatoes are pumped into a preheat tank, go through a centrifugal pump, and are shot out at about 50 mph (80 km/h) at stationary blades which chop the potato into what the industry calls "strips." This invention, called the "Lamb Water Gun Knife," made F. Gilbert Lamb, the founder of Lamb Weston -- one of the largest french fry processors -- a very rich man.

Step 6: Inspection (#2). The strips are inspected by video cameras. When a french fry with a blemish is detected, an optical sorting machine time-sequences a single burst of air to knock the bad fry off the production line and onto a separate conveyor belt. That conveyor belt carries the blemished fry to a machine with tiny automated knives that precisely removes the blemish and returns the fry to the production line. Now, the twice-inspected strips are now ready to be processed.

Step 7: Blanching. The strips are carried along on a conveyor belt through a large vat of hot water. The timing and temperature of the blanching is adjusted continually in order to remove excess sugars and to give a consistent, uniform color to the resulting french fries. If the strips do not contain enough natural sugars, sugar is then added in a dip after the blanching process.

Step 8: Drying. The now blanched strips are carried along a conveyor belt to a machine which blasts hot air from both the top and bottom, partially drying the strips depending on the initial water content of the potatoes. An interesting note is that water content adjustments are made

according to the desired end-product. If the french fries are meant to be deep-fried, the water content will be around 70-75%; cooked in an oven, 65-70%; microwaved, 55-60%. The reason has to do with the proportion of water lost through each method of cooking to ensure that all three versions are virtually indistinguishable when served.

Step 9: Par-Frying. The "par fry" or "partial fry" is a cooking stage where the strips are cooked for about a minute and a half in oil that's a bit hotter than normal french fry cooking temperatures. All frozen french fries are par-fried at the manufacturing plant and then fried completely just before serving.

Step 10: Freezing. The final step is blast freezing the partially fried strips. Blast freezing is a method which freezes the french fries which travel down a wire conveyor with air cooled down to about -40° Celsius by compressed ammonia gas so that only a small amount of ice crystals form on the fries and also to prevent the fries sticking together. Blast freezing also helps protect flavor.

Step 11: Packaging. A computer sorter divides the french fries into six-pound batches, and a centrifuge is used to align the fries so that they all point in the same direction. The fries are then sealed in brown bags, loaded by robots into cardboard boxes, which were in turn stacked on wooden pallets and placed in a large warehouse freezer for storage until eventual delivery to a McDonald's or Burger King fast food outlet.

Step 12: Frying. At the fast food outlet, the processed fries are submerged in cooking oil and fried at high temperatures until they become crisp and have a golden brown color. They are then placed in disposable paper containers and sold over the counter to consumers.

There are several points during the above-described process whereby acrylamide is introduced and where the french fry making process itself creates favorable conditions promoting the creation of acrylamide:

Growing. Polyacrylamide, also known as PAM, is widely used by the farming industry in

pesticide formulations and in soil treatment and the predictable residues of the polymer may be found in vegetables such as potatoes. This polyacrylamide in the potatoes may degrade into acrylamide monomer over time. The addition of polyacrylamide to pesticide formulations is considered a trade secret and is rarely reported while the soil treatment in irrigation water covers a million or more acres in the U.S. The U.S. Department of Agriculture (USDA) serves as both promoter and regulator of the use of polyacrylamide in agriculture.

Washing and peeling. The U.S. Food and Drugs Administration (FDA) allows polyacrylamide as a direct food additive and it is used extensively in washing fruits and vegetables and to assist in their peeling. However, the FDA is clear to point out that polyacrylamide is "[n]ot to exceed 10 parts per million in wash water" and should not contain "more than 0.2 percent acrylamide monomer." 21 C.F.R. § 173.315.

Blanching. According to Richard H. Stadler's recent article in Nature, heating asparagine in the presence of sugar (i.e., glucose, sucrose, lactose, galactose, or fructose) resulted in significant amounts of acrylamide formation. Consequently, the artificial introduction of sugar to blanched potato strips creates a condition that favors the creation of acrylamide monomer when the potato strips are later fried.

Water Content. According to Donald S. Mottram's Nature article, the amount of water in asparagine-glucose reactions has a direct relationship to the amount of resulting acrylamide. When there is less water, less acrylamide is created; more water, more acrylamide. As discussed above, if the french fries are meant to be deep-fried, the water content will be around 70-75%; cooked in an oven, 65-70%; microwaved, 55-60%. The reason for the manipulation of water content has to do with the proportion of water lost through each method of cooking to ensure that all three versions are virtually indistinguishable when served. Consequently, french fries processed for deep frying contain the most water content and are thereby most likely to create the most acrylamide.

pH Factor. According to Dr. Robert Brown of Frito Lay's February 2003 FDA presentation, "Formation, Occurrence and Strategies to Address Acrylamide in Food," acrylamide's peak

formation appears to occur in neutral solutions. With a pH under five, acrylamide formation is severely inhibited. Even at the pH of six there is some significant inhibition of acrylamide formation and as you get towards neutral pH, acrylamide formation is maximized at a pH of around seven.

Frying. The high temperatures at which potatoes are par-fried also favor the creation of acrylamide monomer. Acrylamide formation is again effected when french fries are deep fried at McDonald's and Burger King restaurants before serving. Heat lamps further the process.

Flavor. "Natural flavor" is added to french fries to make up for the flavor they lose by being fried purely in vegetable oil and not beef tallow. The "natural flavor" in McDonald's french fries is engineered by International Flavors & Fragrances ("IFF"), the world's largest flavor company. According to Donald S. Mottram's Nature article, products of the Maillard reaction are responsible for much of the flavor and color generated during cooking. This Maillard-driven generation of flavor in cooked foods is linked to the formation of acrylamide. Conceivably, the creation of natural flavors by IFF involves the Maillard reaction which in turn produces acrylamide.

Indeed, when one looks closely at the french fry preparation process, it is not difficult to be left with the impression that it is optimized for the creation of acrylamide.

V

THE PROPOSED REGULATION WOULD THWART THE WILL OF THE PEOPLE

The proposed regulation would exempt french fries and other high-acrylamide content foods from the warning requirement of Proposition 65 even though acrylamide is present in such products at concentrations which greatly exceed the No Significant Risk Level. The proposed regulation would therefore thwart the will of the People that they be informed that french fries contain a chemical known to the State of California to cause cancer, before they are exposed, i.e., choose to eat french fries. The People of California adopted Proposition 65 in 1986 by an overwhelming majority. In so doing, the People allowed companies to poison Californians with carcinogens,

provided that they first gave Californians clear and reasonable warning. Of course, it is only by receiving clear cancer hazard warnings that Californians can exercise their right to choose whether they wish to eat french fries and thus be exposed to high levels of acrylamide. The People expressed their will clearly: "We have a right to know, and companies have to fairly warn us if they are going to expose us to chemicals that cause cancer." The proposed regulation would substitute a paternalistic administrative agency policy judgment that Californians should not be informed of the cancer hazard of acrylamide in french fries (contrary to their expressed wishes at the ballot box), but that this information the People want should instead be concealed from them. CERT submits that OEHHA should not deprive Californians of the cancer hazard information that they desire, as they expressed in voting for the initiative, and thereby surreptitiously repeal or reject Proposition 65.

"A regulation is not valid or effective unless it is consistent with and not in conflict with the enabling statute. Gov. Code § 11342.2. "A regulation conflicts with the statute if it would 'alter or amend the statute.'" *California Teachers Association v. California Commission on Teacher Credentialing* (2003) 111 Cal.App.4th 1001, 1010-1011; *City of San Jose v. Department of Health Services* (1998) 66 Cal.App.4th 35, 42.

CERT submits that the proposed regulation would not be valid, because, in voting for Proposition 65, the People demanded that they be given cancer hazard warnings before they are exposed to carcinogens, and the proposed initiative would deprive them of this right to know they are being exposed to high levels of the industrial carcinogen acrylamide in french fries.

Rather than adopting the proposed regulating and thereby substituting a paternalistic protective policy for the clear will of the People to be informed of the carcinogenic hazard of acrylamide in french fries, OEHHA should follow the letter and the spirit of Proposition 65 by requiring all those who exposed to Californians to acrylamide above the no significant risk level to provide Californians with the cancer hazard warning they demanded, so that Californians can make informed, intelligent health choices and avoid exposure to carcinogens if they choose to do so.

VI

IF OEHHA ADOPTS AN EXEMPTION FOR ACRYLAMIDE FROM COOKING, IT SHOULD NOT APPLY TO ACRYLAMIDE RESULTING FROM FOOD PROCESSING

The proposed regulation would exempt exposures to acrylamide "formed solely from constituents naturally present in food" as a result of cooking. This language is unclear and is drafted in such a manner that it could actually exempt acrylamide exposures which result from unnecessary processing of food and from adding chemicals to food which increase the resulting acrylamide levels. French fries are a prime example. Acrylamide in french fries results not just from frying potatoes at high temperatures, but from the extensive processing of french fries described above before frying. The proposed regulation presents the following ambiguities with respect to french fries:

1. Is that portion of the acrylamide in french fries which results from growing potatoes in polyacrylamide "formed solely from constituents naturally present in food"?

2. Is that portion of the acrylamide in french fries which results from washing and peeling potatoes with a polyacrylamide solution "formed solely from constituents naturally present in food"?

3. Is that portion of the acrylamide in french fries which results from infusion of artificial sugars into potatoes "formed solely from constituents naturally present in food"?

4. Is that portion of the acrylamide in french fries which results from reducing the water content of potatoes and thereby promoting acrylamide production during frying "formed solely from constituents naturally present in food"?

5. Is that portion of the acrylamide in french fries which results from processing of potatoes which increases the *pH* factor "formed solely from constituents naturally present in food"?

6. Is that portion of the acrylamide in french fries which results from flavoring potatoes with chemicals to enhance taste "formed solely from constituents naturally present in food"?

If OEHHA adopts the proposed regulation, it should clarify that consumer exposure to acrylamide resulting from these processes is not intended to be exempt from the warning requirement of Proposition 65.

VII

IF OEHHA ADOPTS AN EXEMPTION FOR ACRYLAMIDE FROM COOKING, THE EXEMPTION SHOULD ONLY APPLY WHERE THE CONCENTRATION OF ACRYLAMIDE IS REDUCED TO THE LOWEST LEVEL ACHIEVABLE BY APPLICATION OF STATE OF ART KNOWLEDGE AND TECHNOLOGY

The proposed regulation would create an exemption where acrylamide results from cooking and "the concentration of the chemical in question has been reduced to the lowest level currently feasible using good cooking and manufacturing processes."

It is unclear whether the language, "the lowest level currently feasible using good cooking and manufacturing processes," is intended to refer to a standard of common practice, a standard of due care, a standard reflective of currently used state of art technology, or a standard based on such technology as can be achieved by application of the best state of art knowledge and technology.

CERT submits that if OEHHA decides to adopt a proposed regulation exempting acrylamide from cooked food, the language of the regulation should be clarified to reflect that the exemption should not apply unless the manufacturer proves that the level of acrylamide in the food has been reduced to the lowest level possible by application of the best state of art knowledge and technology, rather than some unprotective standard of common practice or due care.

Recent research has demonstrated that application of state of art technology can massively reduce the acrylamide content of french fries. See, e.g., Biedermann, M., et al., "Experiments on Acrylamide Formation and Possibilities to Decrease the Potential of Acyrlamide Formation in Potatoes," *Mitteilungen aus Lebensmitteluntersuchung und Hygiene,"* in press (2004) ["Conclusion: Acrylamide formation can be reduced at modest costs. For potatoes, a combination of better raw material and improved cooking practices should result in an average improvement by at least a factor of 10. . . . With carefully selected potatoes and improved methods of preparation in the kitchen, a massive reduction of acrylamide concentrations can be achieved."]; Amrein, T.M., et al., "Potential

of acrylamide formation, sugars, and free asparagine in potatoes: a comparison of cultivars and farming systems," *J. Agric. Food Chem.* 51(18):5556-5560 (2003) ["It is concluded that acrylamide contents in potato products can be substantially reduced primarily by selecting cultivars with low concentrations of reducing sugars."]; Taubert, D., et al., "Influence of processing parameters on acrylamide formation during frying of potatoes," *J. Agric. Food Chem.* 52(9):2735-2739 (2004) [frying potatoes with intermediate to high surface-to-volume ratios above 180 degrees C or using prolonged processing times substantially decreased acrylamide levels].

The mere fact that available technologies which can reduce the acrylamide content of french fries are not currently being used by the fast food industry is no justification for exempting french fries from Proposition 65. No food product that contains high levels of a carcinogen should be exempted from Proposition 65 where technologies exists which can substantially reduce the level of the carcinogen in the product and those technologies are not being used to reduce the level to the lowest concentration that can be achieved by application of state of art knowledge and technology.

VIII

CONCLUSION

For all the foregoing reasons, OEHHA should reject the proposed exemption as contrary to the will of the People and the letter and spirit of Proposition 65. However, OEHHA adopt an exemption for exposures from chemicals that form from natural constituents in food during cooking or heat processing, the regulation should be revised to provide that acrylamide which is produced as a result of food processing other than cooking or heating is not exempted and that the exemption will only apply where application of state of art technology in cooking and food preparation is used to reduce acrylamide to the lowest level that can be achieved by modern science (as opposed to mere "good cooking and manufacturing processes"). Otherwise, the exemption would allow the food industry, without providing cancer hazard warnings to consumers, to unnecessarily expose

Californians to high levels of acrylamide in foods even though the technology exists to greatly reduce their acrylamide content. An exemption should certainly not license and empower food manufacturers to expose Californians to unnecessarily high levels of acrylamide.

DATE: April ____, 2005

METZGER LAW GROUP
A Professional Law Corporation

_____
RAPHAEL METZGER, ESQ.
Attorneys for COUNCIL FOR EDUCATION AND RESEARCH ON TOXICS (CERT), a California public benefit corporation