

attachment: letter to the FDA in support of petition

June 4, 2003

The Honorable Mark McClellan, M.D., Ph.D.
Commissioner
U.S. Food and Drug Administration
Room 14-71
5600 Fishers Lane
Rockville, Maryland 20782

Dear Dr. McClellan:

Over a year ago Swedish scientists discovered acrylamide in Swedish food. In 1994, the U.S. Department of Health and Human Services' National Toxicology Program determined that acrylamide is reasonably anticipated to be a human carcinogen,¹ and last year the Food and Drug Administration ("FDA") decided that in terms of neurotoxicity a person's safe daily intake for acrylamide is 12 micrograms.² The FDA has now confirmed the presence of acrylamide in various classes of foods, including some baby foods and some infant formulas. Accordingly, we write in support of the petition by the Center for Science in the Public Interest asking that the FDA establish interim acceptable levels of acrylamide in the categories of food that provide the most acrylamide in the American diet.

The Norwegian government has estimated that in Norway dietary acrylamide could cause 450 lifetime cancers per million people.³ Because of differences in dietary patterns and contamination levels between Norway and the United States, that estimate may be somewhat lower or higher than what is valid for the U.S.⁴ Nevertheless, it indicates that the lifetime cancer risk of acrylamide in the United States is well in excess of the one-in-a-million standard that the FDA uses in certain other contexts.⁵ Moreover, the amounts of acrylamide the FDA has found in various foods indicate that the average daily consumption of acrylamide is well in excess of the FDA's safe level based on neurotoxicity.

FDA's discovery of acrylamide in some infant formulas and some baby foods is especially disturbing because: (1) babies may rely on those foods for a substantial proportion of their overall diets, (2) babies tend to consume more food in proportion to their body weights than adults, (3) babies may be more sensitive to the carcinogenic action of acrylamide, and (4) babies may be more sensitive to the neurologic impact of acrylamide because of their immature nervous systems.

The FDA has found large brand differences in the amount of acrylamide present in common foods.⁶ For example, for baked French fries the highest level of 1,325 parts per billion (ppb) is 11 times the lowest level of 119 ppb. For potato chips the maximum level of 2,510 ppb is 21 times the lowest level of 117 ppb. For unbrewed coffee the highest level of 359 ppb is 7 times the lowest level of 51 ppb. For baby food the highest level is 130 ppb, while the lowest level is 0. For infant formula the highest level is less than 10 ppb, while the lowest level is 0. We note that those highest levels deliver amounts of acrylamide well in excess of what would be delivered by drinking water under the 0.5 ppb ceiling that the Environmental Protection Agency

set in 1991.

This wide range of observed values of acrylamide within a particular class of food indicates that it should be possible for the firms with the highest amounts of acrylamide to substantially reduce it.

In conclusion, we urge you to use those observed brand differences in the amounts of acrylamide within a particular class of food as the basis for setting interim acceptable levels of acrylamide in french fries, potato chips, and certain other classes of food. The FDA should set more protective limits for infant formula and baby foods.

Sincerely,

Richard Clapp, M.P.H., D.Sc.
Professor of Environmental Health
Boston University School of Public Health
Boston, Massachusetts

Samuel S. Epstein, M.D.
Professor emeritus, Environmental and
Occupational Medicine
University of Illinois at Chicago School of
Public Health, and
Chairman, Cancer Prevention Coalition
Chicago, Illinois

Dale Hattis, Ph.D.
Research Professor
George Perkins Marsh Institute
Clark University
Worcester, Massachusetts

Kim Hooper, Ph.D.
Hazardous Materials Laboratory
Department of Toxic Substances Control
California Environmental Protection Agency
Berkeley, California

James Huff, Ph.D.
National Institute of Environmental Health
Sciences
Research Triangle Park, North Carolina

R. David Pittle, Ph.D.
Senior Vice President, Technical Policy
Consumers Union
Yonkers, New York

David Suzuki, Ph.D.
Professor Emeritus
University of British Columbia
Vancouver, British Columbia

The signatories' institutions are given for identification purposes only and do not constitute an endorsement on the part of the institutions of information contained in this letter.

Endnotes

1. "Acrylamide," *Report on Carcinogens*, 10th ed. (National Toxicology Program 2002). That same year the World Health Organization concluded that acrylamide is probably carcinogenic to humans. "Acrylamide," *International Agency for Research on Cancer Monographs*, Cas No. 79-06-1, vol. 60 (1994) at 389.
2. 67 Fed. Reg. 42715 (June 25, 2002) (approving acrylamide-acrylic acid as a food additive).
3. *Risk Assessment of Acrylamide Intake from Foods With Special Emphasis on Cancer Risk*, Report from the Scientific Committee on the Norwegian Food Control Authority (June 6, 2002). The Norwegian experts estimated the lifetime cancer risk to be 5 cancer cases per 10,000 Norwegian males and 4 cancer cases per 10,000 Norwegian females.
4. Using food-consumption data from the United States Department of Agriculture and industry, and the amounts of acrylamide that the FDA found in various food categories, the Center for Science in the Public Interest estimates that the average American consumes between 29 and of 37 micrograms a day. Using EPA's cancer slope factor for acrylamide of 4.5/1,000 indicates that acrylamide may cause up to about 8,900 cancers per year. See CSPI petition.
5. 21 C.F.R. subchapter E part 500, subpart E (Regulation of Carcinogenic Compounds Used in Food-Producing Animals).
6. *Exploratory Data on Acrylamide in Foods* (FDA/CFSAN, December 4, 2002) and *Exploratory Data on Acrylamide in Foods - February 2003 Update* (FDA/CFSAN March 12, 2003).
7. 56 Fed. Reg. 3526 (January 30, 1991), codified at 40 C.F.R. 141.50. EPA set the limit because of concerns about acrylamide's likely carcinogenic and neurologic effects on humans.