UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

Reply Brief to June 4, 2003 Petition of the Center for Science in the Public Interest to Establish Interim Acceptable Levels for Acrylamide in Major Food Sources	))))	Docket No. 03P0276

Submitted by the

CENTER FOR CONSUMER FREEDOM

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REPLY BRIEF TO CITIZEN PETITION

1. PRELIMINARY STATEMENT

The Center for Science in the Public Interest (CSPI) has purposefully and knowingly misled the U.S. Food and Drug Administration (FDA) and the American public with its flawed and deceptive petition regarding theoretical human cancer risks associated with dietary acrylamide.

In its June 2003 petition to the FDA and news release, CSPI made the following glaring errors:

- CSPI assumes that acrylamide in food has been conclusively linked to cancer in humans. In fact, there is no peer-reviewed science that bears out this assumption.

- CSPI's calculations presume that the highest levels of acrylamide ever found in French fries or potato chips are always found in every sample. In fact, wide variations are found from brand to brand and even from batch to batch.

- CSPI knowingly underestimated the average American body weight in order to *overestimate* acrylamide's theoretical carcinogenic effects.

- CSPI consciously used outdated methods of determining cancer risk, failing to acknowledge that risks vary by a population's age.

- CSPI intentionally omitted some government nutrition data from its analysis, and intentionally "adjusted" other data in order to inflate its estimates of how much acrylamide Americans ingest daily.

2. BACKGROUND

On June 4, 2003, CSPI's leadership held a press conference to announce that it had formally petitioned the U.S. Food and Drug Administration, asking that agency to force food manufacturers to limit the amount of acrylamide in their products. CSPI made its full FDA petition[1] available to the media, along with a press release[2] and an "expert letter"[3] co-signed by seven handpicked scientists.

Among these so-called "experts" is University of Illinois public health professor Samuel Epstein, who is ranked as America's least credible scientist on issues of environmental cancer by the respected American Association for Cancer Research (AACR). AACR is a scientific society of over 19,000 laboratory and clinical cancer researchers, and the publisher of five leading clinical, peer-reviewed cancer research journals.[4]

Epstein has claimed unproven cancer risks from food irradiation, hot dogs, Ritalin, flea collars, non-organic foods, and non-organic shampoo. He has claimed that the cancer risks from using cosmetics and deodorant are equal to those associated with tobacco. In addition to AACR, the American Cancer Society, the U.S. Food and Drug Administration, and the Canadian Royal College of Physicians and Surgeons have all published statements debunking Epstein's numerous false and misleading claims.

(A.) Reckless Claims

Despite the fact that global public health bodies (including the FDA itself) have not reached consensus on dietary acrylamide's potential human health effects[5], CSPI president Michael Jacobson declared in his press release: "acrylamide probably causes on the order of a thousand new cases of cancer per year in the United States, perhaps as many as several thousand." CSPI's petition to the FDA is more specific, claiming that "dietary acrylamide causes an estimated 8,900 cancers per year" among Americans.

The mass media responded by quoting Jacobson's estimates in over 200 print and broadcast stories during the following week.[6]

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[1] http://cspinet.org/new/pdf/acrylamide_petition.pdf

[2] http://www.cspinet.org/new/200306041.html

[3] http://cspinet.org/new/pdf/expert_letter_on_acrylamide.pdf

[4] http://www.aacr.org/1000.asp

[5] http://vm.cfsan.fda.gov/~dms/acryline.html

[6] http://news.google.com; http://www.nexis.com; http://www.factiva.com

This was not the first time Jacobson has publicly attributed such a large number of cancers to food-based acrylamide. In January 2003 he told a Canadian radio audience that "Tens of thousands of people over the life time of Canadians" were contracting cancer from the acrylamide in their diets.[7] CBC reporter Wendy Mesley responded by asking Jacobson: "How do you work that out when something is not a proven human carcinogen?" Jacobson replied by conceding: "We may never have data on humans."

(B.) Absence of Data

Despite CSPI's insistence that acrylamide presents a clear and present danger to Americans who enjoy certain foods, there are in fact *no* reliable data linking acrylamide in food to a risk of cancer in human beings.

In May 2002, a group of Swedish scientists discovered concentrations of acrylamide in several common, starchy foods. Their initial speculations about carcinogen-like effects were based exclusively on high dose studies in laboratory animals. And in an unusual step, the results of these tests were rushed out to the media without the typically prudent step of subjecting them to peer review and publication.

A few weeks later, the World Health Organization issued a statement cautioning: "The limited data available at this moment does not, however, present us with a full picture, neither of the formation of acrylamide in food or of the consequences to human health."[8]

Indeed, more than 12 months later, there is still no scientific evidence that acrylamide in food causes human cancers at *any* level of exposure. Although the Swedish findings have been confirmed by similar tests in other countries, these have merely established that acrylamide is "there."

(C.) Extrapolating Risk to Humans

According to Joseph A. Levitt, Director of the FDA's Center for Food Safety and Applied Nutrition (CFSAN), existing guidelines calling acrylamide a "probable human carcinogen" are based solely on animal studies, in which significant cancer risk was observed in rats at a "lifetime daily dose" starting at 500 micrograms per kilogram of body weight.[9]

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[7] January 14, 2003, Canadian Broadcasting Corporation, "Market Place"

[8] Press release: "Joint WHO/FAO Global Expert Consultation on Acrylamide in Foods," June 19, 2002; accessed at http://www.who.int/inf/en/MA-2002-09.html

[9] Presentation by CFSAN Director Joseph A. Levitt, "Assessing Acrylamide in the U.S. Food Supply," September 30, 2002; accessed at http://www.cfsan.fda.gov/~dms/acrytran.html#levitt

For a 154-pound human (what CSPI claims is "average"), this equates to a lifetime daily dose of 35,000 micrograms, or 35 milligrams. Judging from the Swedish expert group's results, later confirmed by CSPI, a human being would have to consume over 180 pounds of French fries (or 312 pounds of Cheerios cereal) each day, for life, in order to approach the lowest level of risk observed in laboratory rats.

Even if it were practical for humans to ingest enough food to reach a danger threshold for acrylamide, it would be irresponsible to issue targeted health warnings about specific foods or specific brand names. The FDA has already recognized that acrylamide levels vary widely from food to food and from brand to brand. A February 2003 document issued by CFSAN notes that "unit to unit variation" and "lot to lot variation" have also been observed.[10]

Furthermore, CSPI's assumption of a 70-kilogram (154-pound) body weight for "average" Americans is unrealistic. Current government data from the National Health And Nutrition Education Survey (NHANES) indicate that the average U.S. man and woman weighs 180.7 and 152.3 pounds, respectively.[11] This works out to more than a 75-kilogram average, revealing CSPI's distortion of more than 7 percent. The effect of underestimating Americans' weight is to *overestimate* the amount of acrylamide absorbed per kilogram of bodily tissue.

This blunder is particularly ironic, considering that CSPI has gone out of its way in recent years to claim that America is in the throes of an "obesity epidemic."

3. WILLFUL MANIPULATION

A complete reading of CSPI's June 4 FDA petition shows how the organization "worked out" its numbers. In a remarkable admission, CSPI acknowledges that it consciously manipulated government nutrition data. This allowed CSPI to arrive at acrylamide consumption estimates that better reflected its well-known antagonism toward food producers.

CSPI began with the U.S. Department of Agriculture's "Continuing Survey of Food Intakes by Individuals" (CSFII) for the years 1994 through 1996. Working under the assumption that the typical American weighs 70 kilograms (154 pounds), CSPI interpreted the CSFII data to mean that the average U.S. resident ingests 29 micrograms of acrylamide per day from nine major food categories.

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[10] "Exploratory Data on Acrylamide in Foods - February 2003 Update," March 13, 2003; accessed at http://www.cfsan.fda.gov/~dms/acrydat2.html

[11] NHANES data from 1988 to 1994, updated in May 2003. See http://www.cdc.gov/nchs/data/nhanes/t2.pdf and http://www.cdc.gov/nchs/data/nhanes/t3.pdf

Then, this stunning admission:

> "Because participants in dietary surveys like CSFII typically underestimate food intake, especially of low-nutrition foods like French fries and potato chips, we also adjusted CSFII consumption data in proportion to adjusted energy requirements ... Total consumption comes to 37 micrograms per day."[12]

CSPI first attempts to justify this distortion by claiming the Institute of Medicine's figures on energy and macronutrients dictate that Americans *must* be eating more than the CSFII survey suggests.

Second, CSPI claims that food industry retail sales and "disappearance" data suggest more food is being produced and sold than Americans admit consuming. This conclusion, however, fails to account for spoilage, discarded food, or food exports—any of which is a plausible explanation for CSPI's presumed data gap.

In both cases, CSPI claims that Americans eat 37, not 29, micrograms of acrylamide daily. Without this arbitrary switch (representing a substantial 27 percent increase), Jacobson and CSPI would not be able to claim that dietary acrylamide is responsible for thousands of cancers annually in the United States.

4. OTHER SCIENTIFIC AND ETHICAL BREACHES

CSPI arbitrarily disregarded an enormous, time-tested data set that didn't happen to yield radical enough conclusions for its desired media splash. But this wasn't the only problem with its petition to the FDA. There are several other errors in the group's methodology, and dishonest moments in its text:

(A.) CSPI purposely limited itself to 1994-96 CSFII numbers, knowing fully that including available data from 1998 would have resulted in lower acrylamide intake numbers.

In February 2003, the FDA's Food Advisory Committee Meeting on acrylamide heard a presentation by Dr. Donna Robie of the government's Center for Food Safety and Applied Nutrition. Dr. Robie showed that the data from 1994-96, combined with the 1998 CSFII numbers, together indicated an average daily acrylamide intake of only 25.9 micrograms[13]—even lower than the 29 micrograms suggested by the 1994-96 data alone. Given that CSPI's authors consciously neglected the more recent data, this omission was plainly willful.

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[12] CSPI petition, page 10

[13] 0.37 micrograms per kilogram body weight per day, presuming CSPI's 70-kilogram "average" body weight for the sake of consistency. See http://www.cfsan.fda.gov/~dms/acryrob2/sld021.htm

(B.) CSPI misstated the conclusions of a 1999 study on acrylamide and cancer, admitting its own sleight-of-hand in a footnote.

CSPI claimed "an epidemiological study" has "provided the first evidence that acrylamide might cause (pancreatic) cancer in humans"[14] [parentheses in the original]. This is not true. CSPI concedes in a footnote that the authors of its cited 1999 study "did not find an association between acrylamide and cancer," referring instead to a *re-evaluation* of the original study's data, described in a 2001 letter to the original publication's journal.

(C.) CSPI admits that its chosen method of estimating cancer risk is outdated.

Immediately after concluding that "dietary acrylamide causes an estimated 8,900 cancers per year, or 670,000 over the [U.S.] population's lifetime," CSPI concedes that "using more recent EPA methods for projecting cancer-risk findings may result in estimates several-fold less."[15] How CSPI justifies using an outdated and retired EPA risk-assessment model is never explained.

Lost in CSPI's capricious choice of older methodologies is any sense that cancer risk varies with age. Countless studies have demonstrated that young people have a significantly lower risk profile; furthermore, all carcinogens are associated with "cumulative" risk, which increases with age. Thus, any risk should be adjusted according to the age distribution of the population ingesting a given food.

In the cases of French fries and potato chips, CSPI's constant targets, it should be obvious that younger populations eat these foods more frequently than older populations. Thus, risk assessment of acrylamide from these sources should be *decreased* accordingly.

[14] CSPI petition, page 6

[15] CSPI petition, page 12

(D.) CSPI's chosen FDA "remedy" deliberately ignores the unpredictable distribution of acrylamide concentrations in processed foods.

In its FDA petition, CSPI proposes a regulatory regime that would force manufacturers of foods in any given category (*e.g.*, French fries, potato chips, freeze-dried coffee grounds) to lower their products' acrylamide content to levels that are below the national average for that category. What's more, the group asks the FDA to *continuously lower the legal threshold* each time food producers at the top end of the acrylamide spectrum change their products' contents. "Thus," the petition demands, "with each iteration the interim acceptable level will fall."[16]

Here, reality becomes a stumbling block. "Acrylamide levels," notes a June 4 Associated Press story, "are highly variable, fluctuating from brand to brand *and even batch to batch* [emphasis added].[17] Indeed, during the February 2003 FDA Food Advisory Committee Meeting on acrylamide, Cornell University's Dr. J. Antonio Torres noted:

> "[W]e know there is so much variability between lot-to-lot and batch-to-batch within the same food … I find it a little bit concerning that we may be sending messages on data we really don't know. We are saying, Product XXX has so much, and we really don't know …"[18]

The truth is that asking food manufacturers to control the acrylamide content of individual branded products is not as simple a matter as CSPI suggests—and may very well result in entire classes of processed foods becoming cost-prohibitive to produce and sell. With respect to French fries and potato chips, this is precisely what CSPI wants. The authors of CSPI's petition conveniently avoid any discussion of their proposal's economic impact, noting curtly that "none has been requested by the [FDA] Commissioner."[19]

5. RECENT SCIENCE

The most ambitious study on the health effects of dietary acrylamide to date was published in the January 2003 issue of the *British Journal of Cancer*. Harvard's Dr. Lorelei Mucci described her study's bottom line to a Reuters Health reporter: "This study provides some evidence that the amount of acrylamide people are taking in is probably not sufficient to raise the risk of cancer."[20]

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[16] CSPI petition, page 4

[17] http://www.newsday.com/news/health/ats-ap_health14jun04,0,6785924.story

[18] Advisory Committee proceedings, transcript archived at http://vm.cfsan.fda.gov/~dms/acrytra3.html

[19] CSPI petition, page 20

Mucci's conclusions read (in part) as follows:

> We found consistently a lack of an excess risk, or any convincing trend, of cancer of the bowel, bladder, or kidney in high consumers of 14 different food items with a high or moderate acrylamide content … Unexpectedly, an inverse trend was found for large bowel cancer, with a 40% reduced risk … We found reassuring evidence that dietary exposure to acrylamide in amounts typically ingested by Swedish adults in certain foods has no measurable impact on risk of three major types of cancer.[21]

"No measurable impact" is a clear, definitive statement, especially when combined with the "inverse trend" observed in colon (bowel) cancer.

It should be noted that CSPI released a statement immediately following publication of the Mucci study, insisting that (like most investigational disease studies) it had several built-in limitations.[22] True or not, CSPI's was the only notable voice dismissing what was then the most significant and authoritative acrylamide research to date.

More recently, an Italian study published in the *International Journal of Cancer* questioned the relationship between fried potatoes (*e.g.*, French fries, potato chips) and various human cancers. Absolutely no correlation was found.[23]

Lead researcher Claudio Pelucchi of Milan, Italy, wrote that his team's data "provide reassuring evidence for the lack of an important association between consumption of fried/baked potatoes and cancer risk." This hospital-based, case-control study examined cancers of the oral cavity and pharynx, larynx, large bowel, breast, and ovary.

Although the *International Journal of Cancer* study was first reported to the public via a Reuters News Service story on July 5, 2003[24], it was first published in March—well in advance of CSPI's alarmist petition. CSPI's scientific team either neglected its duty to conduct a through review of the scientific literature, or (more likely) ignored it entirely.

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[20] "Study doubts acrylamide in food causes cancer," January 28, 2003, archived at http://www.upmccancercenters.com/news/reuters/reuters.cfm?article=1218

[21] "Dietary acrylamide and cancer of the large bowel, kidney, and bladder," archived at http://www.nature.com/cgi-taf/DynaPage.taf?file=/bjc/journal/v88/n1/full/6600726a.html

[22] News release, "CSPI on Harvard Acrylamide Study," archived at http://www.cspinet.org/new/200301281.html

[23] "Fried Potatoes and Human Cancer," C. Pelucchi et al; abstract archived at http://www3.interscience.wiley.com/cgi-bin/abstract/104083949/START

[24] "Study Finds No Link Between Cooked Potatoes, Cancer," archived at http://story.news.yahoo.com/news?tmpl=story&u=/nm/20030705/hl_nm/potatoes_cancer_dc_1

6. CONCLUSION

CSPI's alarmist report to the FDA on the "dangers" of acrylamide is scientifically bankrupt, and should be disregarded wholly by regulators. The organization has a long history of attacking companies that produce the foods Americans enjoy most. This latest stunt, while devoid of any scientific basis, illustrates CSPI's now-legendary biases.

The FDA should use this episode to make an example of CSPI, focusing on the tactics it uses to alarm consumers without any scientific basis. Organizations purporting to act "in the public interest" should be held to a high standard of scientific literacy and ethical conduct. In this case, CSPI has demonstrated neither. The public should be increasingly wary, and the government should decline to act upon petitions as ill-informed as CSPI's.