



September 1, 2009

Dear Mr. Kaiser,

I am writing on behalf of NSF International regarding the article entitled, ***“Scientist Tied to Chemical Group: Toxicologists did BPA Safety Review as Paid Consultant,”*** which was published in the August 23, 2009, edition of *Milwaukee Journal Sentinel*. This letter is over 2,500 words long, and while we do not expect it to run in its entirety, it is a reflection of our profound disappointment in the inaccurate and misleading journalism that you have allowed to take place at the *Journal Sentinel*.

By way of background, NSF International is an independent, not-for-profit organization that has a 65-year history of protecting and improving the public's health and safety. The article inaccurately implies that NSF defers to industry in the course of its important work. It also incorrectly implies that Dr. Calvin Willhite, a nationally-renown toxicologist who conducted a risk assessment on BPA for NSF, is affiliated with the chemical industry. He is not.

The truth, which we freely shared with your reporters, is that NSF International is an independent, not-for-profit public health organization that develops national standards to protect the public health in the areas of food, water and indoor air safety. NSF International also tests and certifies products to ensure they meet national and international standards. NSF is a World Health Organization Collaborating Centre for Food and Water Safety and Indoor Environment.

NSF takes its public health mission very seriously. NSF is accredited by the American National Standards Institute (ANSI), which is the U.S. member of the International Organization for Standardization (ISO). ANSI coordinates the development of standards in the U.S. via a Joint Committee process that requires representation from health officials, regulators, academia, scientists, industry, and consumer groups.

NSF also is an ANSI-accredited, third-party certifier that evaluates products for toxicological safety and verifies that they meet the national standards. Manufacturers pay the costs associated with testing and certification. NSF standards, methods and procedures are very rigorous and products not meeting the standards are not certified. ANSI and NSF's other accrediting bodies conduct thorough audits of NSF records and its laboratories to ensure proper procedures are followed at all times. (A similar example is Underwriters Laboratories, which writes standards for electrical products and test products to ensure they meet those standards.)

Included among the many American national public health standards NSF helped develop are the health effects standards that set limits for any materials or chemicals coming into contact with drinking water (NSF/ANSI Standards 60 and 61). In 1988, the U.S. Environmental Protection Agency (EPA) replaced its own Drinking Water Additives evaluation program with these standards that were seed funded by EPA. Many states and public utilities require that manufacturers who make products that come into contact with water have these products tested to verify they meet the national standards.

It is because of the Drinking Water programs that NSF tests for BPA in any component that may contact drinking water, and one of the many types of materials that NSF evaluates is polycarbonates. As part of the evaluation process, NSF utilizes federally-established (EPA or FDA) Maximum Contaminant Level (MCL) of a chemical in drinking water to verify that consumers are not being exposed to levels in excess of regulated levels. NSF Standards 60 and

61 provide a mechanism for establishing an MCL for a contaminant when no federal level exists. Because there was no federal drinking water MCL for BPA at that time, NSF conducted a Risk Assessment on BPA in 2007, as prescribed by NSF Standard 61, to establish drinking water standards for use in NSF testing and certification.

NSF International contracted with Dr. Calvin Willhite, a respected toxicologist with expertise in reproductive and developmental toxicology, to conduct a Human Health Risk Assessment of BPA along with two NSF toxicologists. Willhite holds a Ph.D. in pharmacology from Dartmouth Medical School, a M.S. in toxicology from Utah State University, and has numerous professional and scientific affiliations, including the National Toxicology Program, National Academy of Sciences and U.S. EPA appointments to advisory boards. He is extremely qualified for the type of review he was asked to perform. Willhite, a senior toxicologist for California's Department of Toxic Substances Control, consults with NSF International on matters directly related to NSF's Drinking Water Additives program, which as previously explained, sets limits for contaminants in drinking water.

Dr. Willhite and the two NSF International toxicologists conducted the BPA Risk Assessment in accordance with National Academy of Sciences and EPA Risk Assessment protocols. NSF International funded the risk assessment. Neither Dr. Willhite nor NSF received any compensation from industry, trade association or other organization to conduct this risk assessment. It took nearly two years to complete the risk assessment, which consisted of reviewing published scientific papers and studies on the toxicology of BPA through the third quarter of 2007. The risk assessment revealed that thousands of studies have examined the impact of BPA to determine its effects on laboratory animals. Researchers have performed these studies using both oral and injected doses of BPA. They determined that it is important to distinguish between these two methods of administration as research has shown that the toxicity of BPA differs greatly depending on whether the chemical is administered to lab animals orally or it is injected directly into the bloodstream. Different things happen to the chemical depending on how it makes its way into and through the body.

For example, when BPA is administered to laboratory animals orally, the chemical first passes through the gastrointestinal (GI) tract to the liver where it is conjugated (combined) with glucuronic acid, rendering it pharmacologically inactive and converting it to a very water soluble compound that is readily excreted in the urine. Therefore, when administered orally, BPA generally leaves the body (in urine) without significant circulation in the blood stream.

On the other hand, when BPA is administered to laboratory animals by injection it enters the blood stream directly, does not pass directly through the GI tract or the liver, is not rendered pharmacologically inactive, and can circulate in the bloodstream for a significant period of time before reaching the liver to be conjugated and excreted. Hence, it is far more toxic when injected directly into the bloodstream.

Because 99% of the general population's exposure to BPA is through oral ingestion of food or beverages, as opposed to being injected, the NSF Risk Assessment determined that studies involving the oral route of administration are a more appropriate indicator of BPA's toxicity. This is an important distinction, one that unfortunately was overlooked by your reporters.

From the risk assessment, NSF was able to calculate an oral reference dose (RfD) for BPA. An oral reference dose can be converted to drinking water action levels, which is then used to calculate a drinking water standard used to evaluate products that come in contact with drinking water.

NSF's human health risk assessment on BPA (the oral reference dose) was peer-reviewed by several members of the NSF Health Advisory Board, an independent, unpaid volunteer group of highly-respected toxicologists who provide NSF toxicologists with additional scientific advice and

expertise. Because Dr. Willhite is also a member of the NSF Health Advisory Board, he did not participate in the peer review of the risk assessment he helped perform.

Dr. Willhite and the two NSF toxicologists submitted the BPA risk assessment to the *Journal of Toxicology and Environmental Health*. As noted by the *Journal Sentinel* reporters, Dr. Willhite is on the editorial board for this publication. As one of the country's leading toxicologists, Dr. Willhite has editorial appointments with many leading toxicology publications: *Toxicology and Applied Pharmacological Toxicology*, *Toxicology Letters* and *Reproductive Toxicology*. It makes sense that the NSF risk assessment was submitted to the *Journal of Toxicology and Environmental Health* (JTEH) since it focuses on toxicological and environmental health issues and publishes risk assessments of this nature. The *Journal of Toxicology and Environmental Health* article was peer-reviewed by the Journal's editor and five anonymous scientists, whose identities were known only to the editor, prior to publication.

With that background shared, I now turn to the article appearing in the August 23rd edition of the *Milwaukee Journal Sentinel*, the headline proclaiming: **"Toxicologist has ties to chemical group; Toxicologist did BPA safety review as a paid consultant."**

Rather than address the science behind the NSF International BPA Risk Assessment, something Dr. Willhite repeatedly offered to explain to the reporters, they instead chose to weave a story constructed of partial quotes, misconstrued facts and innuendo aimed at discrediting both Dr. Willhite and NSF. Following are several examples:

In the headline, **"Toxicologist has ties to chemical group,"** and lead paragraph, your reporters state that Dr. Willhite is tied to the chemical industry. Specifically, *"...American Chemistry Council, nominated Willhite and several other scientists whose work they paid for to sit on a panel for the National Toxicology Program's review of BPA safety."* First, Dr. Willhite has never received any payment from the American Chemistry Council. Second, your reporters cite as sole proof of Willhite's alleged ties to this group, the fact that an American Chemistry Council (ACC) representative once suggested Willhite participate in a review of BPA that was being conducted by the National Toxicology Program, which is part of the U.S. Department of Health and Human Services.

As shared with your reporters, Dr. Willhite is a member of the National Toxicology Program's Science Advisory Committee and serves as a panelist at their Center for the Evaluation of Risk to Human Reproduction. He is a widely-regarded expert on the topic throughout the scientific community. The fact that his name was mentioned as a potential panelist by someone at ACC who happened to know of him does not prove ties to the chemical industry. A full retraction of the statement and the headline, as well as a written apology is in order to set the record straight.

We also request that references to both Dr. Willhite and NSF International be removed from the "BPA Connections" graphic that accompanied the article. The copy atop this graphic says the chemical industry has financed studies regarding BPA. NSF's Risk Assessment on BPA was fully-funded by NSF International. As stated earlier, neither Dr. Willhite nor NSF received any compensation from any industry, trade association or any other organization to conduct this risk assessment, nor were we influenced by any agency or association. Further, neither Dr. Willhite nor NSF is affiliated with the STATS organization, as also alleged on this chart.

The second part of the headline, **"Toxicologist did BPA safety review as a paid consultant,"** makes it sound as if Dr. Willhite was a paid consultant from industry, which clearly is not so. Dr. Willhite is employed as a toxicologist by the State of California and consults with NSF on matters related to public health because he has specific expertise in developmental and reproductive toxicology. It is regrettable, yet noteworthy, that the article fails to mention his impressive qualifications, choosing instead to imply he is a chemical industry consultant. We request a retraction of this as well.

The article goes on to incorrectly assert that NSF International **“allows the industry to set its own standards,”** which is totally untrue and enormously misleading. As shared with the *Journal Sentinel*, NSF International is accredited by the American National Standards Institute (ANSI) to develop American national standards. ANSI has an established framework that must be adhered to when developing consensus-based American national standards, which requires input from all affected stakeholders, including public health officials, regulators, scientists, industry and consumers. To state that the process puts “profits over public safety” is a complete misrepresentation of ANSI’s rigorous process and an affront to NSF’s 65-year history of protecting and improving public health and safety. This comment should also be retracted, with a written apology.

To further support their notion of bias, your reporters point to a partial quote from me (Dr. Lori Bestervelt, an NSF Toxicologist) regarding the risk assessment, which they believe implies deference to the industry. They write, **“The company issued a press release quoting Lori Bestervelt, a senior vice president, saying, ‘We are delighted by the results of this study.’”**

In fact, my complete quote in the press release issued by the Journal of Toxicology and Environmental Health was, **“We are delighted by the results of this study and by the impact this new reference dose will have in the evaluation of BPA in products that come in contact with drinking water. However, more research is needed (particularly in reproductive and developmental toxicology) to assess the human health effects of other exposure routes.”** My meaning is clear when given the full quote; however, your reporters chose to selectively excerpt to support their obvious bias. We consider this sloppy journalism at best, and malicious behavior at worst. We certainly hope your newspaper’s standard is higher than this.

In addition, the selective excerpting did not stop there. Asked to clarify this quote, NSF spokeswoman Greta Houlahan is quoted as saying, “Dr. Bestervelt was happy to have completed the two year study of all the available science.” Actually, Houlahan’s complete quote was, “Dr. Bestervelt was happy to have completed the two-year study of all the available science, **the results of which gave us a more current and accurate BPA reference dose against which to test products that come into contact with drinking water in order to prevent adverse health effects.**” Again, when taken in full, we have a quote that in no way implies deference to the industry. This is inexcusable and reflects a malicious intent. If not retracted, we request that full quotes be attributed to both Houlahan and me.

Your reporters continued their apparent quest to discredit Dr. Willhite by writing, “A review of conflict of interest statements shows that Dr. Willhite has not always been transparent about his associations. Forms obtained by the *Journal Sentinel* show that Willhite did not reveal his payment from NSF International on statements filed with the California Fair Political Practices Commission. He did, however, report travel expenses he received as a member of NSF International’s Health Advisory Board.”

Again not so; Dr. Willhite has been completely transparent in reporting his NSF consulting work to his employers in California. The form to which they refer requires that California employees report any income they receive from organizations whose activities are subject to regulation or oversight by the DTSC. NSF activities are not subject to regulation or oversight by Willhite’s department. In fact, Willhite had approached the Department of Toxic Substance Control Legal Office years before, asking them to review and clear his work with NSF prior to beginning it, so as to ensure no conflict of interest existed. The DTSC said there was no conflict. (A separate line item does require Willhite report any travel for which he is reimbursed, which he did.)

Houlahan clearly explained this to your reporters yet her response was paraphrased as “...Houlahan said the California EPA office where Willhite works **investigated** his association with the company...and found there to be no conflict.” The term “investigated” was not used by Houlahan when explaining that Dr. Willhite had initiated a request to have the NSF work approved by his employer prior to beginning it. This entire section should be retracted.

The article also says, “*Dr. Willhite refused repeated requests for comment.*” While Dr. Willhite did not wish to respond to repeated efforts to imply conflict or bias, he did offer to explain the science behind the BPA risk assessment, an offer that was never accepted.

A final attempt to discredit and defame Dr. Willhite and NSF was your reporters’ statement, “*NSF International cites as proof of Dr. Willhite’s authority and impartiality that his study was published in the Journal of Toxicology and Environmental Health, Part B. But the Journal Sentinel has found that Dr. Willhite sits on the editorial board of that same publication.*”

As one of the nation’s leading toxicologists, Dr. Willhite has editorial appointments with several toxicology publications, a fact shared with the *Journal Sentinel*. The NSF risk assessment was submitted to the *Journal of Toxicology and Environmental Health* because it focuses on toxicological and environmental issues, and publishes risk assessments of this type. The article was peer-reviewed by five anonymous scientists, all of whom were selected by the Journal’s editor, and by the editor himself, prior to publication. This is a standard practice in the world of scientific research publication. Dr. Willhite had no input into the peer-review process and to imply it was less than stringent is a disservice to Dr. Willhite and to the *Journal of Toxicology and Environmental Health*, a highly reputable publication.

All of the information outlined in this letter was shared with your reporters Ms. Kissinger and Ms. Rust. Yet at no point in the article did they attempt to strike a balance by referencing NSF’s 65-year public health and safety history, or by presenting Dr. Willhite’s impressive credentials in the field of reproductive and developmental toxicology.

The scientific process is all about debating science findings and, as a scientist, I welcome this. It is only through healthy debate that science moves forward. It is unfortunate that rather than trying to understand the science behind NSF’s Risk Assessment, and explaining it to your readers, the reporters instead resorted to unprofessional tactics and gimmicks aimed at getting headlines instead of truth. The final result of your newspaper’s misrepresentation of the science is a disservice to Dr. Willhite and the hard working scientists at NSF International, which have worked very hard for many years to protect and improve human health. It also is a disservice to your readers. We expect more from a news organization of the *Journal Sentinel’s* caliber and reputation, and we look forward to action on the items requested above.

Sincerely,

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