SCIENTIFIC MISCONDUCT IN THE FLUORIDE IN DRINKING WATER REGULATION by Robert J. Carton, Ph.D., Vice-President, NFFE Local 2050 Box 76082, Washington, D.C. 20013 (202)382-2325. August 19, 1991.

The fluoride in drinking water standard, or Recommended Maximum Contaminant Level (RMCL), published by EPA in the Federal Register on Nov. 14, 1985, is a classic case of political interference with science. The regulation is a fraudulent statement by the Federal Government that 4 milligrams per liter (mg/l) of fluoride in drinking water is safe with an adequate margin of safety. There is evidence that critical information in the scientific and technical support documents used to develop the standard was falsified by the Department of Health and Human Services and the Environmental Protection Agency to protect a long-standing public health policy. EPA professionals were never asked to conduct a thorough independent analysis of the fluoride literature. Instead, their credentials were used to give the appearance of scientific credibility. They were used to support the predetermined conclusion that 4 mg/l of fluoride in drinking water was safe.

Ethical misconduct by EPA management included the following: they ignored the requirements of the law to protect sensitive individuals such as children, diabetics or people with kidney impairment. Contrary to law, they made the criteria for considering health data so stringent that reasonable concerns for safety were eliminated. Data showing positive correlations between fluoride exposure and genetic effects in almost all laboratory tests were discounted. By selective use of data, they fit science to the desired outcome. They reported to the Administrator data demonstrating that dental fluorosis was an adverse health effect, but then hid this information from the public when the Administrator decided to call dental fluorosis a "cosmetic" effect. The National Institute for Dental Research had warned EPA that admitting dental fluorosis was an adverse health effect would be contrary to the long-standing policy of the Public Health Service that fluoridation at 1 mg/l is totally safe. EPA had already admitted in the Federal Register that objectionable dental fluorosis can occur at levels as low as 0.7 mg/l.

EPA management based its standard on only one health effect: crippling skeletal fluorosis. In setting the safe level at 4 mg/l, however, they ignored data showing that healthy individuals were at risk of developing crippling skeletal fluorosis if these individuals happened to drink large quantities of water at the "safe" level of 4 mg/l. EPA's own data showed that some people drink as much as 5.5 liters/day. If these people ingested this amount of water containing 4 mg/l of fluoride, they would receive a daily dose of 22 mg. This exceeds the minimum dose necessary to cause cripplig skeletal fluorosis ("20 mg/day for 20 years") according to EPA and the Public Health Service. This situation is made worse by the fact that there are additional sources of fluoride exposure, such as toothpaste, tea, etc. Even more unsettling is the fact that there is no sound scientific basis for a 20 mg/day threshold. The threshold is probably lower. There is evidence, ignored by EPA, that exposure to fluoride at 1 mg/l in drinking water over a long period of time may calcify ligaments and tendons causing arthritic pains (the earliest clinical signs of skeletal fluorosis).

EPA management also relied upon a report from the Surgeon General which they knew was false. This report claimed to represent the conclusions of an expert panel (on which EPA was an observer) when in fact the concerns of this panel for the effects of fluoride in the bones of children, for its effects on the heart, for dental fluorosis, and for the overall lack of scientific data on the effects of fluoride in U.S. drinking water were deleted. There are indications that a number of important conclusions of the panel were altered without their knowledge or approval.

This instance of scientific fraud is one example of the unethical and unprofessional atmosphere existing at EPA. There are many others. The fluoride standard however is particularly deplorable because of the widespread complicity of a number of different Federal agencies at the very highest levels in distorting the assessment of fluoride's health effects, and thus threatening public health. The Union's involvement in this is not a matter of meddling in the rights of management to dictate policy. We are attempting to correct a clear cut example of management abuse of authority. We insist that professionals have a right to an ethical and professional workplace.

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CARPET EMISSIONS TOXICITY

In 1987-1988 EPA installed 27,000 sq. yds. of carpet at its Waterside Mall Headquarters. People complained immediately about irritation to their eyes, nose and throat, headaches, nausea, dizziness, memory loss and other effects. Though other renovation activities were going on at the same time, EPA air monitoring (May, 1988 through November 1988) showed only carpet-related 4-phenylcyclohexene (4PC) to be uniquely associated with the reported adverse effects. EPA files held a 1987 University of Arizona report showing that 4PC-containing carpet was associated with "numerous" reports of adverse effects in that state. By Fall 1988, a dozen EPA employees had acquired multiple chemical sensitivity (MCS), a debilitating condition of hypersensitivity to many environmental contaminants. EPA established a policy of not using 4PC-containing products in its Headquarters, but denied knowledge that 4PC or carpet causes adverse effects in people.

EPA and the Consumer Product Safety Commission began a regulatory investigation in May 1989. Review by the Union revealed that the investigation would not use air monitoring or employee injury data gathered at EPA Headquarters. When Union President and Senior Scientist Hirzy pointed this out he was ordered not to attend any more work group meetings. He continued to report to the group, however, on numerous contacts received in the Union office from the public about adverse effects from carpet installations in homes, offices and schools. After considering various courses of action and information available on 4PC and its chemical relatives, the Union decided to file a petition under section 21 of the Toxic Substances Control Act, asking EPA to regulate and to order certain testing of carpet.

EPA denied the petition, citing the "anecdotal" nature of the human data on adverse effects from carpets and testing done on rats showing that they did not die after exposure to air levels of 4PC higher than levels to which humans are exposed. EPA and the Center for Disease Control stated in the denial of the petition that there were no epidemiological data showing adverse effects from carpet emissions. Three studies were then found by the Union, two showing excess deaths among carpet workers from lymphocytic leukemia, a disease of the immune system, hypothesized as the site of action of MCS by some investigators. Concurrent with denial of NFFE's petition, EPA convened the "carpet policy dialogue", involving NFFE, industry groups, other Federal agencies, advocacy groups and researchers, charging the group to study emissions from carpet and ways of lowering society's exposures to them by non-regulatory processes, and forbidding investigation of health effects. After inviting Hirzy to represent the Union on the dialogue, EPA now threatens him with prosecution for allegedly violating 18 USC 205, which prohibits representation of private parties on official time.

Since replacement of the 4PC carpet at Headquarters by polyurethane carpet, no more EPA employees have reported adverse effects from carpets. EPA refuses to study cases reported to it by the public, insuring its continued ability to deny that it has any information that carpet can cause adverse health effect in humans, its own massive, 1989 study, done in conjunction with Yale University and NIOSH, showing a link between carpet and employee complaints notwithstanding. If EPA acknowledges adverse effects, it must regulate, thus placing industry at substantial risk in numerous toxic tort actions.

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I am an EPA scientist who is an authority on environmental tobacco smoke. Because my work impacted the tobacco industry adversely, in 1987 the Tobacco Institute, behind the scene, asked Congressman Don Sundquist to make spurious accusations against me, in a letter to EPA's Administrator, Lee Thomas concerning alleged "conflicts of interest." These accusations were transmitted to me through my supervisor, and I responded to them fully in writing. EPA decided that my written rebuttal was inadequate to satisfy the Congressman, and ordered the Inspector General (IG) to investigate me. process of this investigation, which was unbelievably assigned to a chain-smoker, all of my word processor disks, 40 in number, were confiscated, and I was forced to laboriously copy them, one-by-one, on the IG's antiquated equipment, which took on the order of 1/2 hr per disk. About half-way through the investigation, the Agency instituted smoking restrictions, partly as a result of my activities. The chain-smoking investigator was so annoyed that he quit his job and went to another agency which had no restrictions. However, he was allowed to continue to participate in my case, with another investigator from EPA.

I cooperated fully with the investigators, and was cleared of all of the Congressman's allegations after a 7 month investigation. However, outrageously, on the basis of statements I had allegedly made to the investigator, I was found "guilty" of conducting a business on government time. This false finding was not based on any admission of mine, but was in fact a conclusion reached by the investigators, based on the fact that I had also engaged in outside employment from time-to-time, which was approved by the Agency. However, on the basis of my statement to the investigator that I spent 10% of my government time on my research publications, the IG ridiculously concluded that my research publications explicitly part of my performance standards -- consitituted an outside business activity, because they also formed part of the basis for expert witness activities which I engaged in. Initially, the IG had turned over the results of its investigation to the Justice Department for criminal prosecution, but DOJ declined to prosecute. Although the IG's conclusion was ludicrous on its face, my supervisor was instructed to institute disciplinary action; and Upon receipt of my supervisor's notification did so. disciplinary action, I retained an attorney to assist me in overturning the disciplinary action, and was ultimately successful in convincing him to rescind it. However, the whole investigation was very unpleasant, and in my view, totally unnecessary, incompetently conducted, and a complete waste of the government's resources.

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AEROSOL FLAMMABILITY

I initially encountered this problem after CFCs were banned from aerosols and other products due to their breaking down of the ozone layer. The only available substitutes for the CFCs in aerosols were hydrocarbon gases: propane, butane, isobutane, etc. In the process of reviewing a pesticide aerosol I noticed that although the product was 25% propane, there was no warning as to any potential for flammability of the product. Checking with chemists and the regulations, I discovered that EPA (and the Consumer Product Safety Commission, FDA) test and label only for the flammability of combustible liquids. Under the regulations of these Agencies the hydrocarbon gases which are extremely and intensely flammable and explosive and solids such as gunpowder and sulfur (both found in pesticide products) are not labeled with regard to their flammable/explosion hazards.

In the late 70s and early 80s I had tried to get my immediate supervisor and then my Branch Chief to do something about this situation (without success). By 1984 in response to a woman who had been severely burned by a leaking can of raid under her sink (the propane/isobutane mixture ignited from the pilot light when she went to investigate the "hissss" under her sink and the resulting explosion threw her out of the room and left her with second degree burns on exposed skin), I sent a paper on the subject to then regulations writer Janet Auerbach. This paper outlined the problem and suggested appropriate changes in the regulations so that all three states of matter, gases and solids as well as liquids be labeled as to flammability. This paper was never even acknowledged and later I was told by Auerbach that she ignored my paper because she considered me a "trouble maker". I later found out as a result of an Office of Special Council complaint I submitted that a colleague of mine Tyrone Aiken had submitted a similar paper regarding the flammability/explosiveness of sulfur. Similarly, Mr. Aiken's paper was ignored and the OSC, despite discovering two independent cases of Auerbach's failure to act on identified safety hazards, found no pattern of mismanagement!

By 1987 I finally got my Division Director Edwin "Rick" Tinsworth to take action on this issue. A Notice was issued but since manufacturers were given no opportunity to comment, the notice was later recinded with the agreement that industry and the Agency would meet again in 6 months and compare proposed

precautionary language for these products.

In the meantime, a reorganization took place which gave me a new branch chief and a new division director. Both my former branch chief and division director came to me and informed me that they had briefed their replacements on my issue. When the deadline had passed (more than 6 months overdue) for meeting again with industry, I wrote a memo updating my new managers BC Ferial Bishop and DD Anne Lindsay. Bishop refused to forward the memo to Lindsay so I copied the memo and sent it to Lindsay directly. Both denied having knowledge of the issue. When I grieved the incident I was taken out of my job of Product Chemistry (where I was in direct contact with the issue) and given a largely clerical job. Bishop informed me in answer to my grievance that the workload was such that I was no longer needed in chemistry but I was needed in the new section. When I demonstrated that the chemisty backlog was increasing at a dramatic rate and that I had no work assignments in the new section, I was transferred to reviewing toxicology data, a position for which I am unqualified and which puts the public at risk. (See Hartz Blockade Issue)

Presently, the Agency has issued a Federal Register Notice outlining proposed testing and labeling requirements. Although I wrote the notice and developed the testing and label precautions, on the final draft my name was deleted and Donald Stubbs was substituted, thereby depriving me of my deserved

recognition on this issue.

There have been hundreds of burns and property damages, a number of deaths, and at least two innocent housewives charged with arson as a result of management's failure to act sine at imply manner to the second s

HARTZ BLOCKADE ISSUE

Hartz Blockade for Dogs and Hartz Blockade for Cats were both registered on May 12, 1986 without the appropriate toxicology data to support registration. These data were necessary in that the two previously registered active ingredients were for the first time present in a product together.

On November 28, 1986, in response to a letter of complaint to the California Department of Food & Agriculture concerning dog and cat deaths due to the Hartz Blockade products, entomologist Phil Hutton indicated that the product should not cause any problems due to the low toxicity of the active ingredients (fenvalerate and DEET) in these products. This is interesting in that I am an entomologist as is Phil Hutton. Mr. Hutton's assignment at that time was the same as mine is now: to review acute toxicity data. I haved insisted (citing OPM regulations) that I am unqualified by education and training to review toxicity data. Management insists otherwise.

On September 18, 1987, professional toxicologist Byron Backus outlined an extensive battery of toxicity tests which Hartz needed to perform on its products. These tests were in response to the known deaths of 75 pets and hundreds of cases of sub lethal poisoning in others.

In December 1987 Hartz announced its plans to reintroduce the Blockade products on the market after a period of removal. Last check of the files (more than a year ago) indicated that Hartz was still submitting toxicity data in September and October of 1989, more than 3 years after registration.

This issue outlines several important deficiencies in the registration of pesticide products:

I have been severely retaliated against for my refusal to carry out my illegal job assignment which might put the American public at risk. This situation of unqualified personnel performing important (affecting human health and the environment) scientific functions is widespread throughout the Office of Pesticide Programs.

A recent check of 15 radomly selected products registered in the last 5 years indicated that 13 of the 15 did not have all the data to support registration. This helped to precipitate an audit by EPA's Inspector General; this audit has been quashed by the Assistant Administrator of the Office of Pesticides and Toxic Substances Linda Fisher.

Upper management in the Office of Pesticide Programs is scientifically untrained. Registration Division Director, Anne Lindsay, for instance, has a BA in English, yet regularly makes scientific decisions such as my (and others) being qualified to do tasks which I (and others) are not qualified to do. She also makes the final decision as to what pesticides and in what amounts these pesticides can occur on food!

The Hartz Blockade scandal is illustrative of what can happen in an atmosphere of inadequate scientific review and mismanagement. With Blockade it was dogs and cats, next it may be people or environmental catastrophe...

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SCIENCE REPRISALS AND FIRST AMMENDMENT RIGHTS AT EPA

Rufus Morison, Ph.D., Senior Ecologist and Chief Steward

The background for the EPA-IG reprisal against me for expressing my scientific opinion was the result of a local controversy about the use of a chemical pesticide, Dimilin^R (diflubenzuron), to control gypsy moth in Alexandria and elsewhere.

In 1976-77 after review of data, I opposed registration because of extreme high toxicity and other effects on the ecology of insects, crabs and probable genetic effects. Despite these concerns and human health concerns expressed by others, it was registered for limited use in forest plantations. That use did not include urban exposure.

The public debate was whether to use no controls or biological, chemical or a combination. The controversy was long and heated. The City Council opted to use biological pesticide, *Bacillus thuringiensis* (BT) and Dimilin^R the first year (Spring 1988) and all biological controls in the years following partly as result of the efforts of the Committee Opposed to Dimilin^R of which I was a member.

My October 1988 letter to Pat Durkin, Editor of the Alexandria Gazette-Packet and remarks made to neighborhood associations and to the City Council of Alexandria were strongly in support of biological control and against Dimilin^R and chemical control advocated by the State and EPA.

Among the scientific studies I presented at the meetings and in Alexandria Gazette-Packet the were results of an National Toxicology Program study on an environmental breakdown product of diflubenzuron. It reported that the Dimilin^R breakdown product induced rare cancers in animals. EPA management officials refuted any risk concerns and appeared at public meetings in Fairfax to express EPA's confidence in the safety of Dimilin^R. Uniroyal representatives attended some meetings and presented non-technical material showing the untoward effects of the gypsy moth. (Gypsy moth poses no known risk to humans and very little risk to urban trees.)

The IG investigation from an anonymous Hot Line complaint was conducted under the theory of possible violation of 40 CFR Section 3.506(c), which requires that writing or editing, whether related to an employee's official duties or not, must either omit mention of the employee's official title or affiliation with the Agency, or include a disclaimer. No consideration seems to have been given to whether this statute genuinely could be made to apply to a letter to the editor of a local newspaper, by a local resident having specialized knowledge, and writing concerning a local issue. Certainly neither the statute itself nor the EPA Standards of Conduct contain any language that could reasonably be construed as applying to either a letter to the editor or rising to speak briefly and informally in a "town hall" hearing or meeting. Could disciplinary action properly have been taken against me based upon the circumstances, and could such action have been sustained against a First Amendment challenge? Probably not, so the question arises why this investigation was pursued to such great length.

I consider that this investigation was a misdirection of resources, in that it pursued me as an individual, rather than a viable, well-articulated, set of allegations against me; the distinction is important. Finally, it is my opinion that the investigation violated my constitutional rights to free speech and due process, as well as some of those same rights of the members of the Committee Opposed to Dimilin^R, a group of citizens living in Alexandria, Virginia.

During this time I served as Senior Vice President and Chief Steward of Local 2050, National Federation of Federal Employees. I was told by Rob Denney Of EPA that the IG investigation was a reprisal for Union activities.