UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



WASHINGTON, D.C. 20460

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OFFICE OF SOLID WASTE AND EMERGENCY RESPONSE

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Mr. Stephen D. Ramsey, Vice President Corporate Environmental Programs General Electric Company 3135 Easton Turnpike Fairfield, CT 06431

RE: Health Effects from PCBs

Dear Mr. Ramsey:

Thank you for your letter to EPA Advanistrator Carol M. Browner of May 19, 1998. At the Administrator's request, I have prepared this response to your letter regarding health effects from PCBs. EPA believes that the General Electric/Housatonic River site poses a significant public health threat due to PCB-related contamination. The public health must be protected from this threat through several immediate and longer-term cleanup actions. I hope that GE will resume negotiations with our Region I office and begin the planning, engineering design and other activities necessary to undertake removal activities at the plant site, river and floodplains in order to conclude this matter as quickly as possible.

I believe EPA must continue to provide the public with full and accurate information about the public health effects of pollution, including PCBs. EPA strongly disagrees with your assertion that PCBs do not present a significant adverse health risk to humans in Pittsfield or elsewhere. EPA believes that the full body of scientific evidence supports a conclusion that PCBs are a probable human carcinogen and also pose a number of serious non-cancer health risks to intellectual functions, the nervous system, the immune system and the reproductive system. Our New England office recently completed a risk evaluation of human health impacts along a two-mile section of the Housatonic River. The evaluation documents the widespread prevalence and high concentrations of PCBs in and along this section of river and the significant human health risks associated with exposure to those PCBs. The risk evaluation determined that young children and teenagers playing in and near portions of the river face non-cancer risks that are 200 times greater than EPA considers safe. Teenage children growing up near portions of theriver face a 1 in 1000 cancer risk due to exposure to contaminated riverbank soils, and fish collected in the river had PCB concentrations that were among the highest levels ever found in the United States and 100 times higher than the limits set by the U.S. Food and Drug Administration. The risk evaluation supports EPA's conclusion that this section of river may

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present an imminent and substantial endangerment to human health, and is an important component of the Administrative Record which justifies removal actions for the Upper Reach section of the river.

Several issues raised by GE related to PCB toxicity are discussed in greater detail below.

PCB Carcinogenicity

In 1996, EPA completed a reassessment of the carcinogenicity of PCBs. The reassessment reflected EPA's commitment to utilize the best scientific information and risk assessment methodologies in our decision-making. The reassessment confirmed that environmental PCB mixtures are highly likely to pose a risk of cancer to humans, and that PCB congeners bound to sediment and soil and bioaccumulated in fish are likely to present the greatest risks to human health. Human studies, when considered in conjunction with animal studies, support the conclusion that PCBs are probable human carcinogens. As with many human studies, the PCB studies are hampered by a difficulty in defining actual exposure levels and exposure to complex mixtures of chemicals, including different types of PCBs. In all cases, EPA focusses on the complete toxicity database, including detailed, controlled animal studies in order to assess the weight of evidence of carcinogenicity. EPA considers the complete database to be suggestive of carcinogenicity of PCBs in humans. EPA will continue to review the issue of PCB carcinogenicity as new data become available.

EPA is not alone in its concern about the carcinogenicity of PCBs. The International Agency for Research on Cancer (IARC) has declared PCBs to be a probable carcinogen in humans based on sufficient evidence in animals and limited evidence in humans, (IARC, 1987). In addition, the National Toxicology Program (1989) has concluded that PCBs are reasonably anticipated to be carcinogenic in humans based on sufficient evidence in animals. The National Institute for Occupational Safety and Health has determined that PCBs are a potential occupational carcinogen.

PCB Non-Cancer Effects

Detailed, controlled studies in animals have demonstrated immunological, reproductive and neurological effects from PCB exposure. Studies in mice, monkeys, guinea pigs and rabbits have shown PCBs to be immunosuppressive. As is often the case, the human epidemiology studies on PCBs are limited by difficulties in defining actual exposure levels; however, dermal and ocular effects have been observed in humans occupationally exposed to PCBs. These are some of the same effects which have occurred in animals, and there is concern that immune impacts may occur in humans following exposure to PCBs. EPA is concerned about potential neurological effects in humans from PCBs. Animals exposed to PCBs have exhibited neurological effects, such as neurobehavorial deficits, altered levels of neurotransmitters, altered calcium homeostasis, and altered spontaneous motor behavior. It is not known whether these neurodevelopmental effects are reversible and recent human studies have indicated neurological endpoints. EPA, in collaboration with other federal agencies, is supporting research activities to better understand these potential effects.

Several Aroclor mixtures have been shown to cause adverse effects in the reproductive system of monkeys, rats, mice and mink. Female rhesus monkeys showed reduced reproductive performance, including spontaneous abortions and reduced birth weights following exposure to various PCBs. Adverse reproductive effects continued long after dosing had ended, and through multiple generations, suggesting that PCBs can have a lasting effect. The clear evidence for reproductive effects in animals raises concerns regarding the potential reproductive toxicity of PCBs in humans.

Endocrine disruption is a rapidly developing research area which is of significant potential concern to the Agency. While data on PCBs are still limited, there has been significant discussion about the potential for PCBs to cause endocrine effects. The thyroid appears to be a target organ for PCBs in animals. The human occupational data which exist, while limited, support the animal thyroid findings and indicate a potential for thyroid toxicity in humans as well. In addition, most Aroclor mixtures contain dioxin-like congeners which have been demonstrated to alter multiple endocrine systems. EPA and the National Academy of Sciences are currently reviewing the available scientific studies to determine whether a strong link with human effects can be established. EPA will consider the latest data on potential thyroid effects as we move forward in the reassessment of the non-carcinogenic hazards of PCBs.

Massachusetts Department of Public Health (MDPH) studies

GE suggests that several Massachusetts Department of Public Health (MDPH) studies support a conclusion that PCB exposures and health impacts are not occurring in the Pittsfield area. In contrast to GE's characterization of the results of these studies, MDPH stated in their May 15 letter to GE that "...several studies of exposure prevalence done by the Massachusetts Department of Public Health (MDPH) have demonstrated a relationship between increased frequency and duration of activities providing opportunities for exposure and higher serum PCB levels." The letter states further, that "Clearly, the scientific research base for PCBs and other organochlorine compounds presents a number of serious potential health concerns.". While the MDPH results suggest that potentially significant exposures from PCBs may be occurring in Pittsfield, it is inappropriate to use these studies to draw conclusions regarding health risks due to the study design and sample size. In conclusion, EPA believes that the General Electric/Housatonic River site poses a -significant public-health threat due to PCB-related contamination. The public health must-be--protected from this threat through several immediate and longer-term cleanup actions. We are committed to a fair and fast resolution of these issues to fully protect public health and the environment.

Sincerely nothy Rields. Jr.

Acting Assistant Administrator

Carol M. Browner, EPA Administrator John F. Welch, Jr., Chairman and Chief Executive Officer, GE Lois J. Schiffer, Assistant Attorney General, Department of Justice Steven A. Herman, Assistant Administrator, EPA/OECA John DeVillars, Regional Administrator, EPA New England David B. Struhs, Commissioner, Massachusetts DEP

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