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May 19, 1998

The Honorable Carol M. Browner
Administrator
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Re: Health Effects from PCBs

Dear Administrator Browner:

I am writing in response to your May 15, 1998 letter to John F. Welch, Chairman of General Electric Company (GE). We appreciate your response. GE desires to reach a final settlement of this matter and, to that end, GE will shortly be providing Regional Administrator John DeVillars with a new proposal for resolution of the issues at this site. We look forward to positive discussions about our proposal.

As we move forward in an attempt to conclude this matter, nevertheless, we feel compelled to address the statement in your letter that PCBs "pose a number of serious non-cancer health risks". Your letter references a list of alleged effects which, we believe, far from being "linked" to exposure to PCBs, are at most speculative and unproved. EPA itself has noted the uncertainty surrounding the items raised in your letter. Because the existence of an imminent endangerment is key to the Region's intent to order an "emergency" $45 + million "removal" – thereby bypassing numerous required site investigation and evaluation procedures, and the public participation and other opportunities for input to the process – I am providing the following analysis for your information and attention.

An objective review of the significant amount of data regarding human exposure to PCBs shows that PCBs do not present a significant adverse health risk to humans in Pittsfield or elsewhere. To pose a health threat there must be both risk associated with a chemical, and actual exposure to such a chemical at levels sufficient to create harm. Studies by EPA, state regulatory agencies, and numerous independent institutions show that there is no such threat at Pittsfield and certainly there is no threat of imminent endangerment from conditions there to justify abrogation of traditional EPA administrative processes.

Actual Exposure

- The levels of PCBs in the blood of people living in or near the Housatonic River floodplain are no different from background levels for the general population. A 1997 study by the Massachusetts Department of Public Health (MDPH) showed average blood serum PCB levels (the "biomarker of choice" for state and federal regulators) for non-occupationally exposed residents of the Housatonic River area to be 4.49 ppb – at the low end of the national background range (an average of 4 - 8 ppb, with no more than 5% greater than 20 ppb). In fact, according to one internal MDPH report, one woman who had eaten fish from the Housatonic for 75 years was found to have PCB levels within the background range. If people have no greater exposure than the rest of the United States population, then there can be no risk – and certainly no "emergency."

- The 1997 MDPH study is fully consistent with other studies at Norwood, MA, Stratford, CT, Bloomington, IN, Paoli, PA, and other PCB disposal sites. These studies of hundreds of persons who lived in areas with high PCB concentrations have shown that there is a virtually negligible risk that PCBs will get into the human body through soil ingestion, inhalation, or skin contact.

Actual Health Impact

- The State of Massachusetts' assessment of reproductive problems, including infant mortality and reduced birth weight, indicates that these occurrences among Pittsfield residents are no different than those for the rest of the state. This November 1997 report also shows that the overall cancer incidence rate in Pittsfield for the period 1987-1994 was 10% lower than that of the state generally.

In light of these important, recent Pittsfield-specific data on exposure and health statistics, let me now turn to the general relationship between PCBs and both cancer and non-cancer health effects. A careful review shows that neither the cancer nor the non-cancer effects of PCBs on humans have been established – after extensive scientific study in this area.

PCB Carcinogenicity

- Statements that PCBs cause cancer are based solely on animal – not human – studies conducted with high lifetime doses of PCBs. However, even for animals, EPA has recently acknowledged that PCB cancer risks had been

overestimated, when it changed the PCB cancer slope factor in 1996 and reduced the calculated cancer risk by a factor of between 4 and 100.[1]

- More than 20 human health studies, most of which were conducted or sponsored by government agencies such as EPA and the National Institute of Occupational Safety and Health, have failed to conclude that PCBs cause cancer in humans. Among these is a 1997 study by researchers from Harvard University that found no relationship between PCB exposure and breast cancer. See 337 New England J. of Med. 1253 (Oct. 1997).

PCB Non-Cancer Effects

The statements in your letter that PCBs pose a number of non-cancer health risks are unproved hypotheses which will not withstand careful scrutiny and, indeed, EPA has been careful in other contexts not to rely on such non-cancer effects and to question the science in this area. These hypotheses begin with the claim that PCBs are estrogen-mimicking chemicals or endocrine disrupters. These claims have been widely publicized, but subsequent research has resulted in a different view of PCBs than originally reported.

- The Tulane University study which was initially interpreted to conclude that PCBs are synergistic endocrine disrupters has since been withdrawn by its authors because five (5) different laboratories, including their own, failed to reproduce the study's results.

- The Harvard study on PCBs and breast cancer concluded that PCBs are not a factor in breast cancer in women and that PCBs are "very weak" estrogens, requiring concentrations of up to 100,000 times more than the natural estrogen to achieve equivalent estrogenic activity. See 337 New England J. of Med. at 1256 (Oct. 1997). The Harvard study also found that naturally occurring estrogenic compounds in the diet are present at levels many orders of magnitude higher than environmental estrogens. Id.

- Worker studies have not identified any impacts from PCBs on the immune system despite exposure levels hundreds of times higher than current environmental exposure levels.

- Alleged effects on IQ, birth weight, and the reproductive system are based on studies that have been heavily criticized by responsible scientists in government and academia. For example, the Jacobson study of mothers eating Great Lakes fish was flawed by the researchers' admitted failure to

[1] I should note that the Region failed to utilize the revised EPA cancer slope factor in the proposed National Priorities List rulemaking for the Pittsfield/Housatonic site.

screen for toxins other than PCBs in the contaminated fish, and their failure to account for the fact that fish consumers also consumed more alcohol, caffeine, and cold medications and were on average nearly 10 pounds lighter than women in the control group (all of these non-PCB factors could be expected to reduce birth weight).

- The studies that claim neuro-developmental effects associated with low level PCB exposure do not replicate each other's results, and generally used intellectual assessment tools that were not designed for, or validated for use in, population-based research.

- By contrast, a 1997 Dutch study of neurological development of children exposed in utero to PCBs or dioxin concluded that "overt neurological abnormalities found in the neonatal period are not caused by either direct effects of PCB or dioxin exposure or lowered thyroid hormone levels induced by these pollutants." See 39 Dev. Medicine & Child Neurology at 785 (1997).

- EPA's own comprehensive review of the state of the science on this issue concluded in 1997 that, with few exceptions (none of which involved any effects from PCBs), "an adverse health effect in humans operating via endocrine disruption has not been established." See EPA Special Report on Endocrine Disruption (Feb. 1997).

In summary, in the years since PCBs were banned from manufacture and use by the Toxic Substances Control Act, an overwhelming body of both government and independent research has shown that the adverse health effects initially thought to result from exposure to PCBs have been significantly overstated. Many of the scientists who previously believed PCBs to present a significant health risk have changed their minds on the basis of new research. Perhaps the best example of this change in view is that EPA has reduced its assessment of the cancer potency of PCBs. More significantly, the body of scientific evidence which is specific to Pittsfield shows that in the more than 60 years since PCBs were first used there, no adverse health effects have been identified and the overall health of the people in Pittsfield is better than that in other areas of Massachusetts. EPA and the State DEP have repeatedly told the Pittsfield community that normal activities in the River and surrounding areas (e.g. canoeing) are safe.

In short, neither the conditions in Pittsfield nor the science about PCBs can support any claim that there is a health endangerment or risk in Pittsfield which would justify the type of emergency action or removal being considered by the Region. We urge EPA to follow the legally required steps of performing a

thorough and complete evaluation of the site, analyzing all remedial options and the true health risk rather than compelling an environmentally destructive remedy without the type of analysis required by law.

I appreciate the opportunity to make our views known, and I would be glad to respond to your questions on this important subject.

Sincerely,

Stephen D. Ramsey

cc: John DeVillars, U.S. EPA
Steven Herman, U.S. EPA
Tim Fields, U.S. EPA
Lois Schiffer, U.S. DOJ
Jan Reitsma, MA EOEA
David Struhs, MDEP