GE SCIENCE BRIEFS 3/19/97

- 1. PCB Dechlorination in the Upper Hudson River
- 2. Do PCBs Cause Disease in Humans?
- 3. GE's Rat-Feeding Study and EPA PCB Cancer Reassessment
- 4. Neurodevelopmental Effects on PCBs
- 5. PCBs as Environmental Estrogens
- 6. Volatilization of PCBs from Hudson River Sediments

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PCB Dechlorination in the Upper Hudson River

Anaerobic PCB dechlorination is an important part of the natural restoration occurring in the Upper Hudson River. Critical processes include dechlorination, burial, and source control. The main issue remains the source of PCBs to fish.

<u>Issue</u>

- Has dechlorination been confirmed in the Upper Hudson River, and is it limited in extent?
- If dechlorination only reduces the PCB concentration by 10-20%, does it have only a minimal benefit.
- Does dechlorination reduce the risk associated with PCB in sediments?
- Is mass removal the only legitimate approach to reducing the risk of PCBs in the Upper Hudson River?

Apparent loading from the Thompson Island Pool sediments is the problem. Will removal of these sediments accelerate the recovery?

<u>Update</u>

- Widespread dechlorination has been demonstrated with 3 sediment surveys (NYSDEC, GE, EPA). The most extensive dechlorination occurs in areas of highest concentration (hotspots). Dozens of laboratory studies confirm these findings.
- Mass is not the issue, it's risk reduction and reduced exposure to fish and other receptors. Dechlorination may only reduce mass by 10-20%, but it reduces exposure and bioaccumulation > 100 fold.
- Reduced carcinogenicity is strongly supported by new EPA cancer potency values. Non-cancer endpoints are believed to correlate with the levels of specific PCB congeners, and dechlorination directly reduces the concentration of these congeners (>90%).
- Risk is driven by PCB fish levels, and the source of this material
 is the key question. Fingerprinting and reduced
 bioaccumulation show that the aged, dechlorinated, buried
 PCBs are not a significant source. In fact, hotspots have the
 greatest extent of dechlorination and the smallest impacts on
 fish.
- Loading from the Thompson Island Pool sediments is unknown, and is the critical question to be answered to develop the correct remedial solution for the river. This apparent loading (the TIP anomaly) is likely related to the upstream source, and recent data supports this view.

Do PCBs Cause Disease in Humans?

Both clinical examinations of exposed persons and retrospective mortality studies have been carried out. Researchers have selected for study individuals who were exposed to high levels of PCBs before current regulatory controls were established. If PCB exposure is associated with an adverse health outcome, it would be expected to be manifested in these individuals, all of whose exposures began over 20 years ago.

- 7 clinical (morbidity) studies of workers exposed to PCBs
 - PCB blood levels were sometimes > 1000 ppb versus community background levels (10-25 ppb)
 - Contact dermatitis was most frequently diagnosed effect, clearing up when the affected person was removed from direct contact with fluid
 - Major studies carried out at GE Capacitor, Westinghouse Capacitor, and GSA transformer repair shop:

found:

no cases of chloracne

no effects on immune function (GSA)

evidence of enzyme induction (clearance mechanism) - GE and Westinghouse

NIOSH researchers concluded: "Overall, workers exposed to PCBs accumulate serum PCB levels many times greater than background levels, yet a paucity of clinically apparent illness among study participants appears to be the rule."

"One would expect that adverse human health effects from exposure to PCBs, if they exist, would most readily be identified in groups with the greatest exposures (excluding poisoning attributable to accidental contamination of food). None of the published occupational exposure to PCBs is associated with any adverse health outcome, to be distinguished from demonstrable subclinical biochemical alterations."

- 2 clinical (morbidity) studies of fish eaters (Lake Michigan and Connecticut)
 - Studies were conducted in 1970s, when levels in fish were much higher than today.
 - Blood levels of fish eaters reached 366 ppb.
 - No link between adverse health or clinical observations and PCB blood levels.

<u>Do PCBs Cause Disease in Humans?</u> (cont.)

Retrospective Mortality Studies

- The statistical comparison of causes of death in an exposed group (cohort) compared to expected deaths from national standardized death rates.
- 10 exposed worker mortality studies have been conducted worldwide 6 in US of which 5 involved GE plants.

General Findings:

- Mortality all causes: less than expected Healthy Worker Effect
- Cancer Mortality: usually less than expected
- Some individual cancer types elevated, but no consistent pattern across studies
- No finding that cancer risk increases with extent or duration of exposure to PCBs
- None of the investigators claimed a causal association of PCB exposure and cancer deaths

Studies are being updated as the cohorts age. EPA's recent reduction in cancer risk estimates for PCBs is consistent with the mortality experience

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GE Rat-Feeding Study and EPA PCB Cancer Reassessment

While there is no credible evidence that PCBs cause cancer in humans (based on numerous human epidemiological studies), EPA regulates PCBs as "probable human carcinogens" based on results from rat-feeding studies.

In the past, EPA has used data from a study involving Aroclor 1260 to calculate a Cancer Slope Factor of 7.7 (mg/kg/day)⁻¹ and applied this factor to all PCBs, regardless of composition, in risk calculations. This practice was inconsistent with the totality of feeding study data, which indicated that other, less chlorinated PCB mixtures would have lower cancer potency. However, the previous rat-feeding studies were performed following different protocols, including different rat strains, numbers of animals, dose levels, feeding periods, et al. These differences made study-to-study comparisons problematical, even though the diagnosis of the pathology from the previous studies was later determined by a pathology working group.

In order to overcome these shortcomings, GE has sponsored a comprehensive ratfeeding study, involving the four major Aroclors (1016, 1242, 1254 and 1260) that were used in the production of electrical equipment and that represent over 90% of total PCBs sold in this country. The study was carried out at Battelle Laboratories, Columbus, Ohio. In developing the protocol, we sought guidance from scientists from EPA and the National Toxicology Program, the U.S. Government group that conducts such studies for government agencies, and we followed EPA's guidelines for Good Laboratory Practices.

There were multiple dosage levels for male and female Sprague Dawley rats. Rats were killed at different time points in order to study the development of lesions in the liver and other target organs, and to study the retention of PCBs in various tissues on a congener-specific basis. A pathology working group was convened to review the liver pathology and provide a consensus opinion to the toxicology laboratory. The interim analytical work was part of an effort to relate the development of tumors to the build-up of PCBs (on a congener basis) in the animals. For each dose group, we also tested the animals for neurological effects after one year of treatment.

The results of the study are as follows:

- Liver tumors were increased in all female rats except lowest dose (50 ppm) 1016 and only in the high-dose group of 1260 in males. Thyroid tumors were observed in male rats, but did not follow a dose response.
- Tumorigenic response was generally less than observed in previous studies.
- Mammary Gland tumors were generally reduced in treated female rats compared to controls.

GE Rat-Feeding Study and EPA PCB Cancer Reassessment (Continued)

- No evidence of Neurotoxicity.
- PCB-exposed female rats (most affected by liver toxicity) significantly outlived untreated rats.

These data were provided to U.S. EPA in order that they might be considered as part of EPA's ongoing reassessment of the cancer potency of PCBs. Details of the study and its results were reviewed by EPA's Scientific Advisory Panel in May, 1996. The Battelle-GE study was hailed by EPA, environmentalists and scientific reviewers as an excellent study, filling important data gaps, and carried out in a way to ensure credibility and acceptance.

Subsequent to the Advisory Panel meeting in May, EPA released its reassessment of the carcinogenic potency of PCBs, replacing the old slope factor of 7.7 (mg/kg/day)⁻¹ with a range of 0.07-2.0 (mg/kg/day)⁻¹, incorporating data from both the old studies and the new study. EPA advises risk assessors to consider the route of exposure in applying the range of slope factors to PCBs found in the environment. For example, if the exposure route is through fish or soil consumption, the slope factor of 2.0 should be used; for drinking water or inhalation of soluble or volatile congeners, resp., a factor of 0.4 should be used. If the environmental mixture contains no more than 0.5% (by weight) of pentachloro- (or higher) congeners, the factor of 0.07 can be used. Thus, a reduction in slope factor of about 4 to 100 might be justified, depending on the circumstances.

These changes reduce concerns about cancer risk of PCBs, and also provide the opportunity to lower costs of clean-up of contaminated wastes without incurring additional risks.

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Neurodevelopmental Effects of PCBs

General Issue: A study initiated in 1980 reported adverse effects on babies born of mothers who consumed fish from Lake Michigan (Jacobson, 1984). Effects claimed were decreased head circumference and body weight at birth, and reductions in test scores in the Neonatal Behavioral Assessment Scale, related to either the mother's estimates of PCB exposure based on fish consumption, measured PCB maternal or cord blood levels, or both.

Limitations of the Jacobson Studies:

- The chemical analyses were limited to PCBs. Known or suspected neurotoxic agents such as lead, mercury, pesticides, etc., were not measured. In an early paper, Jacobson acknowledged that "it is possible that the behavioral deficits associated with fish consumption are due to toxins other than PCBs in the same contaminated fish." This caveat has been omitted in later papers.
- Analytical capabilities in the early 1980s were crude and often unreliable when PCB levels were near the level of detection. Perhaps for that reason, over half of the cord blood samples were not quantifiable.
- The researchers made the unusual decision to limit the size of the control group to one third that of the exposed group, and further compounded the problem by random selection of controls, rather than matching the control and exposed groups on characteristics likely to have some impact on the physical and neurological measures under study. Exposed women consumed more alcohol, caffeine and cold medication, and weighed on average 4.1 Kg. less than control women prior to pregnancy. Pre-pregnant weight is a strong determinant of birth weight and alcohol consumption is believed to be related to birth weight and cognitive outcome.
- Limitations introduced in the original design of the study cannot be corrected retroactively, and apply to all updates.

Reproducibility of Jacobson Results: None of the later, in some cases, better designed studies reported thus far have reproduced the Jacobsons' results.

Scientific View of the Jacobson Studies: Limitations of the studies have been discussed for years, beginning with Paneth (Michigan State University) in 1991. In 1996, a complete issue of the peer-reviewed scientific journal "Neurotoxicology and Teratology" is devoted to critiques of the Jacobson and similar studies. The study should be judged as a hypothesis-generating study that has not been proven correct by later studies.

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PCBs as Environmental Estrogens

Concerns about possible detrimental effects of synthetic chemicals found in the environment having the potential to alter normal hormonal processes in living organisms have been raised by studies that suggest certain trends and effects. The major effects and the current interpretation of the data are summarized below:

Effects Reported

Reductions in male sperm count and quality over a 40 year period.

- Increases in national breast cancer rates and correlations, in a small, pilot study, of breast cancer with tissue levels of PCBs and pesticides.
- Male trout in English rivers showed female reproductive characteristics (Vitellogenin production) initially believed to be due to breakdown products of detergents having estrogenic properties.
- Male alligators in a Florida lake showed underdeveloped penises, believed to be due to a major spill of a pesticide.

Updates

- Sperm counts are affected by many factors, mostly life style related, that were not properly considered in the original study. It has since been shown that geographical factors are important, with the US > Europe and NYC > California. The decline reported in the original study can be explained by the inappropriate mixing of NYC and European data. No decline has been observed in studies using US data.
- Increases in national breast cancer rates may be explained as a result of increased screening (mammograms). Subsequent, larger scale tests of a correlation of PCB tissue levels with breast cancer have been negative.
- An update of the male trout Vitellogenin production study indicates that natural female estrogens in effluent from sewage treatment plants account for the findings. Synthetic chemicals are not implicated.
- The changes in male alligators in Florida are probably best explained by the very high levels of pesticide spilled into the lake.

PCBs as Environmental Estrogens (cont.)

Effects Reported

- Certain "PCBs" were reported to cause alteration of temperature-dependent sex determination of turtle eggs in laboratory tests.
- <u>In vitro</u> (test tube) studies of mixtures of pesticides and two hydroxy substituted PCBs showed strong, synergistic estrogenic effects in a yeast cell culture.

Updates

- The "PCBs" found to be weakly active in the turtle egg tests were actually hydroxy-substituted PCBs. No PCBs per se, were active. The parent congeners of the active compounds are laboratory specimens not found in commercial PCBs or in the environment.
 - The <u>in vitro</u> tests showing synergies could not be repeated in five other laboratories, including one US Government lab and NYS DOH.

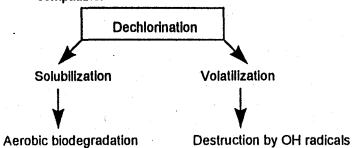
"With few exceptions ... a causal relationship between exposure to a specific environmental agent and an adverse effect on human health operating via an endocrine disruption mechanism has not been established."

-- Special Report on Environmental Endocrine Disruption U.S. EPA. February 1997

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Volatilization of PCBs from Hudson River Sediments

- Issue: Increased risks to health and the environment from PCBs volatilizing from Hudson River sediments has been postulated by New York State scientists. The experimental basis for this concern has not been peer-reviewed or published.
- Volatilization of PCBs contributing to global transport is a wellestablished scientific fact that has been extensively studied over the last 30+ years and reported in peer-reviewed literature. The key issue is whether the net effect of volatilization increases or decreases environmental risk.
- Volatilization is favored by low chlorination level. Thus low chlorine containing PCBs are more likely to be in atmospheric samples. The favored congeners tend not to bioaccumulate in fish or in humans.
- Volatilized PCBs are destroyed in the atmosphere. The
 reaction of PCBs with OH radicals naturally present in the
 atmosphere is believed to be the largest pathway for destruction
 of PCBs in the environment.
 - estimated at 8300 tons of PCB/year globally, or
 16 million pounds.
 - lower chlorinated PCBs are destroyed faster, with half lives around 2 days.
 - Dechlorination and volatilization are beneficially compatible.



- Volatilization does not increase local risks of exposure or estimates of health effects.
 - A study of produce obtained downwind of the heavily contaminated New Bedford harbor did not show elevated PCB levels compared to produce from an upwind source, except during harbor dredging operations.
 - PCB blood levels of people living in areas of high contamination (New Bedford, MA; Bloomington, IN; and around 8 disposal sites) did not show elevated PCB blood levels, compared to the general population.
 - US EPA has assigned a lower health risk to PCBs taken in by inhalation (volatile PCBs).
 - A risk assessment was made (by ChemRisk) for individuals living at the edge of the Hudson River using the maximum estimated PCB volatilization rate and EPA's current estimates of PCB cancer potency and non-cancer risks. The resulting risk estimates were well below US EPA's guidelines for acceptable risks.
- The extent of volatilization and correspondingly, atmospheric PCB levels have decreased over time, based on indirect data. Plant foliage PCB levels, a reliable measure of ambient air levels, have decreased by 50 times in England from 1965-1985. Water levels in Lake Michigan have decreased by over 50% from 1980-1991.

The volatilization of PCBs from sediments is considered, on balance, beneficial, leading to atmospheric destruction and reduced sediment concentration. Local health risks are not affected by volatilization.