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GENERAL  ELECTRIC

CORPORATE RESEARCH AND DEVELOPMENT

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F. D. B.
SCHENECTADY, N. Y. 1
DIAL COMM 8-235

Building K-1, Room 3B35
January 24, 1979

JT Coe
JS Nelson
FAIRFIELD

Subject: Proposed Research on the Differentiation of Toxic from
Non-Toxic Forms of PCB

Dear Jerry and Jim,

Last week you suggested that I amplify upon the proposed PCB/PCDD research program outlined in my letter to Dr. Casey of January 16. Accordingly, I should like to indicate, first, what I think could be accomplished by having such a program; second, what its technical content might consist of; and third, what it might cost to do the job right.

I. Program Objectives

A. The primary objective of this program would be to generate information needed to present OSHA with a non-controversial and face-saving alternative to NIOSH's proposed $1 \mu\text{g}/\text{m}^3$ PCB standard, and thus to avoid an expensive, highly publicized, and possibly unsuccessful legal battle to keep our plants open.

B. Secondary objectives would be to defuse the chronic threats of PCB-related lawsuits resulting from old deposits in dumps or river bottoms, or past exposures to employees, customers, or the general public; and to reduce our public image as a major contributor of toxic material to the environment.

II. Assumed Situation at OSHA

My proposed strategy for achieving the primary program objective assumes that somewhere in OSHA there exists a decision-making individual who is confronting this set of facts:

A. NIOSH has selected from the scientific literature a large number of alarming statements related to the bioeffects of PCB-containing mixtures, written a 224-page criteria document that resembles a political manifesto and a legal brief as much as it does a scientific treatise, and called for a thousand-fold reduction in the permissible exposure level, i.e., down to $1 \mu\text{g}/\text{m}^3$ (about 1 ppb). This document has been sitting in his office, and in those of the lab and environmental activists, since September, 1977.

B. These activists are known to regard the promulgation of ultra-stringent standards as the primary test of Agency commitment, efficacy and machismo. In the case of the ambient water quality standard, EPA fought for six years to get the 1 part per trillion PCB standard in place, and finally made it. Sooner or later, pressure on OSHA to implement the NIOSH 1 $\mu\text{g}/\text{m}^3$ proposal will be inevitable.

C. Recent experience with acrylonitrile and benzene has shown, however, that ultra-stringent standards that go beyond the bounds of any conceivable economic justifiability may not stand up legally.

D. OSHA does not relish big legal fights, nor does it have the legal staff to engage in more than a very few of them. Further, it has no assurance that the forthcoming generic carcinogen rules can actually help avoid such fights in situations with as many unusual elements as that presented by PCB.

The above elements present what many politicians would describe as a "no-win" situation. OSHA's decision maker has responded by delaying action on the NIOSH proposal for at least 18 months, but he can't delay indefinitely without an explanation. I therefore presume that he would welcome a face-saving compromise, and suggest positioning ourselves to approach him along these lines:

III. Proposed Approach to OSHA

A. If we can get our show together before OSHA issues its proposed standard and starts public hearings, we should go down for a visit and make these points:

1. The proposed standard would force the closing and demolition of most US capacitor and transformer manufacturing plants, none of which have used PCB's for 2-3 years. GE and other manufacturers would be forced to fight this vigorously, and would anticipate a fair measure of public and press support for their position.

2. The NIOSH criteria document specifically called attention to the need for additional research on the health effects associated with chronic exposures to PCB's and on the contaminants in commercial PCB preparations. General Electric is actively pursuing both of these lines of research, both in its own laboratories and through collaboration with Dr. Selikoff's group at Mt. Sinai.

3. The preliminary indications are that these studies will demonstrate the need for a standard that will be differentiated according to the measured or presumptive levels of toxic impurities in the PCB. Such a standard could be even more rigorous than that proposed by NIOSH for some PCB mixtures, but more like the present ACGIH and International standards for others. Overall, it would permit at least as great protection of occupational health without need for massive demolition of old plants.

4. Accordingly, we would propose that OSHA defer standard setting until the ongoing research studies have been completed and the results made available for public scrutiny. Such a delay would not produce an obvious health hazard, since PCB manufacture and import into this country was discontinued 18 months ago, and the opportunities for occupational exposure are rapidly declining.

B. If OSHA moves first, hits the Federal Register with a proposed standard, and initiates public hearings, we should expand the above lines of argument to include legal as well as pragmatic issues, for example:

1. OSHA has always recognized, as a matter of stated policy, that substances having generically similar chemical formulae can still be very different in terms of toxic hazard. It has never proposed to regulate any chemical substance, for either toxicity or carcinogenicity except on the basis of biological activities clearly manifested by the substance itself.

2. The available literature on PCB mixtures indicates a very wide range in toxicological properties, including tumorigenicity. This is borne out both by experiments with laboratory animals as well as occupational health experience in American industry. Simply stated, some PCB mixtures are dangerous and some are not.

3. From the time of the very first study of occupational illness caused by a PCB mixture, back in 1933, it was recognized that the characteristic symptoms of PCB poisoning were produced by infrequently-appearing impurities in the PCB. Since 1970 it has been known that the significant toxic impurities in the few cases studied were the polychlorinated dibenzofurans (PCDF's), a family of materials that can be formed in PCB's by certain types of unusual thermal and/or photochemical exposure. The NIOSH criteria document specifically

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pointed out the need for further studies of such impurities. On-going research at Mt. Sinai, NIEHS, and GE itself should permit unambiguous resolution of the role of PCDF's in PCB toxicity, enable us to sort out the toxic PCB mixtures from the non-toxic ones, and thus permit an appropriate regulatory response for each, in accord with usual OSHA policy.

4. We therefore propose that the hearings be recessed until these current research studies have been completed.

IV. Research Studies Needed to Support the Suggested Approach

A. Technical Objective. The objective of the proposed research program would be to produce two manuscripts (or subdivisions thereof, if necessary): both written as if directed at an external scientific and/or medical audience; and both meeting the accepted technical and scholarly standards for publication in reputable refereed journals. One of these studies would be primarily chemical; it would describe an original analytical chemical investigation of the distribution of non-PCB impurities, including PCDF's, in various sorts of industrial and laboratory PCB samples, and show how the results correlated with reported levels of toxic activity. The other study would be primarily medical; starting from existing data on the health status of the Capacitor worker population, augmented by additional epidemiological and control studies as required, it would develop statistics on the incidence of various forms of morbidity and mortality in this special population that was heavily exposed to purified PCB's.

B. The chemical study would include:

1. A critical review of the available toxicological literature, showing the wide range of activities reported for various PCB's (already complete up to 1976).

2. Experimental work to demonstrate the feasibility of doing quantitative analyses for families of impurities (e.g., PCDF's, diphenyl ethers, biphenols, terphenyls, etc.) via minor modifications of the existing perchlorination procedure; also to establish the sensitivity and precision of the assay.

3. Quantitative analyses of several dozen PCB mixtures: e.g., acceptance samples from Hudson Falls, before and after fuller's earth:

treatment if appropriate; specimens of used and unused transformer Pyranol; random laboratory samples that had been stored in glass; and samples of PCB's that had been used for reported animal toxicity studies if we can get them.

4. Qualitative analyses on a few representative samples, done with high resolution GC-mass spec, to identify the major individual species responsible for the generically-quantitated families.

5. Data interpretations and discussion as required, to point out (a) the probable origins of the various impurities found and (b) the correlations between the observed trends in impurity levels and the reported manifestations of toxicity.

C. The medical study can be less sharply delineated at the moment because we have not had access to the available data compilations at either Hudson Falls, Corporate Headquarters, or Mt. Sinai. Thus, the work to be done would have to involve:

1. Assessment of available data banks, covering both Hudson Falls capacitor workers and suitable control populations, in order to determine which forms of epidemiological statistics and statistical comparisons could be conveniently assembled within a year.

2. Development of any necessary joint authorship agreements with the present possessors of the data, whereby we would agree to help with the work of compilation, statistical analysis, and manuscript preparation in return for having the buried data made available and sharing the credit.

3. Direct participation in the allegedly on-going Mt. Sinai matched cohort-pair study of capacitor worker health, if it would appear helpful in getting the job done.

4. Writing reports giving statistical information on incidence (a) suspected manifestation of acute toxicity, (b) chronic health effects, and (c) various causes of death for both capacitor workers and control populations.

U.S. ENV. PROT. AGENCY
WASHINGTON, D.C. 20460
JUL 10 1978

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D. Anticipated Findings. The remarkable scientific paradox presented by PCB is the following: On one hand, PCB mixtures were widely used in American industry for over 40 years, with massive worker exposure, resulting (as we now know from the unpublished Mt. Sinai studies) in correspondingly massive uptake into the workers' bodies, but with total absence of significant health effects at least 99% of the time. The few episodes of toxic manifestations that were noted got reported because they were "news," i.e., recognized by unusual events rather than ordinary, everyday experience. On the other hand, there is equally no doubt at all that many real episodes of poisoning by PCB mixtures have occurred. Typically, these did not simply involve an occasional susceptible individual: when chloracne appeared at all, lots of people got it. There is also no doubt that many laboratory animals have been killed or made sick by PCB mixtures, often at doses that make the very survival of 1937-1977 era electrical workers incomprehensible.

It is our expectation that the proposed chemical and medical investigations will finally provide a satisfying explanation for this mystery, both by providing adequate documentation for the low level of significant health effects in a chronically-exposed population, and also by identifying the origin of the actual hazard. I expect that we will be able to demonstrate a very low level of PCDF and other oxygenated impurities in the electrical-grade PCB's which went into both capacitors and transformers, and hence were involved in occupational exposures in the plant. I anticipate that we will see little PCDF but appreciable polychlorinated biphenols (hydrolysis products that are toxicologically equivalent to PCB's themselves) in the used transformer PCB's. On the other hand, I think we will see appreciable PCDF levels in PCB specimens that have been subjected to high temperature treatment or stored in glass in the laboratory, and also in the specimens - if we can get them - that caused significant toxic response in other people's animal tests. When we put the pieces together, I think we'll be able to show that (a) prolonged occupational exposure of worker populations to purified PCB mixtures at the 200-2000 $\mu\text{g}/\text{m}^3$ level, in addition to dermal contact, resulted in various quantifiable low level health effects, and (b) that the various higher level effects reported in the literature can be shown, either by direct analytical evidence or by reasonable presumption based on specimen history, to be correlatable to PCDF impurity levels. The regulatory implications obviously, would be that sharp reductions in permissible exposure levels to PCB's in old electrical manufacturing plants are not warranted, nor is there much cause for concern over the wastes from

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such plants (or from paper recyclers) that have wound up in dumps or rivers. Conversely, there may still be cause for concern over PCB's that have come out of old heat exchangers, as was true for the Yusho incident in Japan and may also be for the PCB's in Lake Michigan today.

V. Proposed Scope and Staffing

At the present, we obviously do not know precisely how much time would be required for the various individual tasks, and hence cannot estimate how we would allocate effort between, for example, validating the precision of the analyses vs. increasing the number of specimens analysed. Such allocations are not of primary importance in determining project scope, however. The ultimate technical objective is to produce two manuscripts describing original studies that can stand up to peer review by predictably critical audiences. The generation of any such a document in an area outside our ongoing research projects requires a substantial fraction of a man-year of competent professor effort, or distributed equivalent thereof, pretty much independently of how easily the data turns up. Our critics will be judging us by effort expended as well as coherence of argument.

The level of effort I'd propose for a credible study of PCB impurity levels would be 12 person-months of associate staff analytical chemist or skilled technician effort for the quantitative analyses; 1-2 man-months by our highly competent mass spectroscopist, Dr. W.V. Ligon, for the qualitative analyses and analytical chemical consultation, and 1-2 man-months of my own time (unapplied) for program coordination and report writing. At the moment, I am assuming that a credible job on the epidemiological story could be done by our staff M.D., Dick Lawton, in about 6 man-months. Dick has a repeatedly demonstrated ability to march into a complicated medical area, dig out the facts, and come up with an impressive review paper. In addition some technical support might be needed for literature searches and compilations.

This level of effort at CRD would result in roughly 150K of applied costs for the two studies. Certain short-cuts or task eliminations could be contemplated; however, they might not be desirable in view of the ultimate objective desired. It is also quite likely that CRD might be willing to share some of the cost out of its assessed funds. However, the proposed project was not included in the approved 1979 program plan, and I doubt very much whether my management would

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permit me to go ahead with this type of effort unless the great majority were to be paid for by the operating components concerned. What I'd really like to have to do the job right is 150K in external support; that is, 50K each from Capacitor, Transformer, and ASBD, and then to use CRD funds for addressing unanticipated problems and opportunities, e.g., photochemical experiments to demonstrate how PCDF could form in old laboratory PCB samples, or enlargement of the epidemiological effort.

Thus, the decision that you need to make boils down to this: will the Company be better off to spend 150K (from whatever source) on PCB/PCDF toxicity research, so that it will have a strong case to present to OSHA (and other plaintiffs), or should it take a chance on being able to win on grounds of economic hardship alone?

Best regards,

cc: M Aven
EL Simons



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