TALK BY RICHARD J. WIECHMANN
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"A LITTLE LEARNING..."

Many of you will remember from your college freshman English course a quotation by Alexander Pope: "A little learning is a dangerous thing. Drink deep or taste not the Pierian spring." This thought is particularly applicable to environmental matters these days. Time and again, we see that the more we learn about a particular subject -- the less it develops we really know.

This has frequently applied to various environmental "solutions" which, later on, turned out to have unforeseen and dire environmental affects. As one might say, the cure kills deader than the disease.

To look at one specific environmental problem, it may very well be that a proposed rule-making by the Food and Drug Administration, establishing a temporary tolerance for polychlorinated biphenyls - PCB's - in paperboard food packaging, falls into this category.

So let me briefly give you some background on PCB's, describe some of the factors which led up to the FDA issuing the proposed rule-making almost one year ago, and bring you up to date on what has transpired between the FDA and the paper industry since then.

Although the PCB family of chemicals was known before the turn of the century, and commercial production in this country and in the industrial nations of the world began sometime in the late 1920's, it has only been in the last few years that PCB's have become a subject for headlines or have been referred to in speeches on the floor of Congress.

Along with the members of the press and the politicians, the scientific community has also moved PCB's into the spotlight. A good deal of research has recently been done to determine their affects on fish, birds and other wildlife. And, as a result, numerous scientific reports on PCB's are now available.

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To mention just two examples of this recent interest in PCB's, in September 1970, the National Swedish Environment Protection Board sponsored a conference on PCB's investigating all aspects of this chemical compound from its history as a contaminant of the environment to the possible ways of destroying it. Moreover, at the last meeting of the American Chemical Society in New York City, some 30 papers were presented on the subject of PCB's.

PCB's have been manufactured in most of the world's industrial countries. In the United States, Monsanto has been the sole producer, although PCB's have been marketed under private labels by a number of firms in this country. The remarkable properties of the PCB family have made them most versatile as far as their usage is concerned; but, on the other hand, their resistance to chemical, thermal and biological degradation have made them most troublesome when released into the environment.

The discovery of PCB's as an environmental contaminant was made in Sweden in 1966 by Dr. Soren Jensen. Actually they were found by accident while he was analyzing certain biological materials for DDT. This discovery led to investigations which revealed that industrial uses of PCB's were contaminating estuarial waters and, since PCB's are persistent, they were being accumulated in the tissues of marine life and aquatic birds as a result of the food chain syndrome.

Four years after his original discovery of PCB as an environmental contaminant, Dr. Jensen stated that PCB's were almost as widespread in nature as DDT and could be found all over the world.

The one major instance involving acute human exposure to PCB's occurred in Japan in 1968. Kanechlor 400, a PCB containing 48% chlorine manufactured in Japan, leaked from a heat exchanger into rice oil that was consumed by many Japanese families. The rice oil became heavily contaminated in the range of 2,000 to 2,500 parts per million of PCB. About 1,000 people were affected. And

although there were no deaths, some birth abnormalities were recorded. However, it is reported that after three years the children now appear normal in every respect. In that particular case the purity of the PCB was unknown, and there is some question as to whether its toxicity might have been due to the presence of highly toxic polychlorinated dibenzofuran or chloro-dibenzodioxin impurities.

In the United States, the Food and Drug Administration has endeavored to investigate all reported examples of PCB contamination. These have included instances involving milk, eggs and poultry which were contaminated from the use of PCB's in silo paints, or from the use of PCB's for a herbicide, or from PCB fluid leaking from a heat exchanger. Environmental contamination in the United States has been largely associated with surface waters, lakes and estuaries. Municipal and industrial waste water discharges have been primary offenders, together with ordinary incinerators which volatilize PCB's and add them to the atmosphere. In many of the instances where traces of PCB's have been found in paper and paperboard made from virgin pulp, it is presumed that these

PCB's originated in the process water. In this regard, last May, the Environmental Protection Agency declared PCB's to be a toxic substance and announced that the agency will restrict the discharge of industrial effluents of PCB's, so that the levels in waterways do not exceed one hundredeth of a part per billion.

Levels of PCB's were discovered in recycled paperboard in October of 1970. However, it was not until a meeting in early January 1971 of the Biological and Chemical Research Committee of the American Paper Institute that one of the members of this committee reported analytical determinations of PCB's in recycled or combination paperboard and identified the source of this contamination as NCR carbonless copy paper. This NCR copy paper was included in the bales of waste paper used as furnish in manufacturing combination paperboard. It was recommended that the industry adopt defensive measures in the selection of its paper stock for food grades, and, on January 12, 1971, the American Paper Institute advised its membership of the PCB

contamination from NCR carbonless copy paper and urged extreme caution in the selection of waste paper for food grade paperboard.

This major problem for the paper industry resulted from the use of Aroclor 1242, a liquid PCB of 42% average chlorine content, as a vehicle for the dye in NCR carbonless copy paper. Aroclor, incidentally, is a Monsanto brand name. Minute encapsulations containing this PCB with colorless dye were coated on a business form stock. With the pressure of a pen, pencil or typewriter, the encapsulations were crushed exposing the dye to an activator -- which developed the clue color on the receptor sheet. This carbonless copy paper contained 30,000 parts per million, or 3% of PCB by weight. When you realize that one pound of such paper hidden in a bale of paper stock for recycling could theoretically contaminate one and a half tons of paperboard to the extent of 10 parts per million, you will get an idea of the potential problem.

After the discovery of PCB's as an environmental contaminant, interest in and awareness of the ecological incidences of PCB's accelerated in this country. The accidental food contaminations investigated by the FDA received wide publicity and headlines. In May of 1971, the late Congressman William A. Ryan of New York introduced legislation to make illegal the shipment of PCB's in interstate commerce — except as uses for a dielectric in electrical capacitors and as a fire-resistant ingredient in heat transformer media. In September of that year, Ryan introduced another bill which would have totally banned the distribution of PCB's in interstate commerce.

Monsanto, the sole producer in this country of PCB's, had already taken action to restrict their production. As of the first of September of 1970, Monsanto withdrew PCB's from the market for any use other than inclosed systems such as electrical transformers and closed-system heat exchangers. By the first of June 1971, NCR stopped using PCB's as encapsulating agents in their carbonless copy paper.

During the summer of 1971, the Food and Drug Administration was able to document the finding of PCB's in recycled paperboard used as packaging for breakfast cereal, and also to show that there was a migration of the PCB's from the paperboard to the food. This stimulated FDA's field investigations, but at no time did the government instigate a seizure or recall action as a result of food contamination from PCB's in the packaging material.

There were, however, several discussions between the FDA and members of the paper industry with regard to the potential threat of migration of PCB's between the packaging material and the food. Therefore, in December 1971, API's Biological and Chemical Research Committee contracted with the Hazelton Laboratories of Vienna, Virginia, to survey papers and paperboards used in packaging for PCB's. At the same time the B&CR Committee sponsored another study by Hazelton to determine the nature of the migration phenomenon and the barrier effect, over extended periods of time,

of certain films and glassine papers such as are used as inner linings in cereal packaging. This latter study was published in June of 1972. It indicated that PCB migration from packaging materials to food is essentially a vapor-phase adsorption phenonamon. In the absence of an effective barrier, Aroclor 1242 was shown to migrate from paperboard to food in measurable amounts when the paperboard contained a significant amount of the Aroclor. However, by interposing barrier materials, migration to food was significantly reduced. The degree of reduction appeared to be inversely correlated with the known gas permeabilities for the classes of barrier material studied. Of these, PVDC coated paper and waxed glassine paper were found to be effective barriers over a 90-day test period. Polyethylene, on the other hand, was relatively ineffective.

The survey of paper food packaging materials showed that combination paperboard samples contained PCB's in amounts ranging from less than 10 parts per million to over 200 parts per million. It also showed that certain products

made from virgin pulp had definite detectable amounts of PCB's.

Meanwhile, there had been other important developments on the PCB front. At the beginning of September 1971, an inter-departmental task force on PCB's was established, made up of the representatives of several agencies of the federal government. The task force included operating units of five Executive Branch departments -

1. Department of Agriculture

2. Department of Commerce (The Assistant Secretary for Science & Technology and the National Oceanic and Atmosphere Administration)

3. Environmental Protection Agency

4. Department of Health, Education & Welfare (The Food and Drug Administration and the National Institute of Environmental Health Sciences of the National Institute of Health)

5. Department of the Interior (Bureau of Sport Fisheries and Wildlife)

This task force was established in order to coordinate the scientific efforts of the government, aimed at understanding the entire family of PCB's

so as to strengthen the government's ability to protect the public from the actual and potential hazards of PCB's.

As the first order of business the task force indicated that it would "coordinate a government-wide investigation into PCB contamination of food and other products." This study was conducted over the fall and winter and the results were published in May 1972. The full results of this 181-page study would be too much to go into at this time. However, they made two points of specific interest.

First, they recognized the source of contamination in recycled paperboard as having been carbonless copy paper and noted that the use of PCB's in this had been discontinued. Second, while they recognized PCB's as a potential food contaminant, they found that the "dietary intake of PCB's is of low order and does not present an imminent health hazard." They further noted that "to date all of the high levels of PCB's encountered in foods have been associated with accidents."

By the end of September 1971, public interest and political clamor on PCB's had reached sufficient intensity to cause Commissioner Edwards of the FDA to call a press conference. He advised that there was no immediate hazard to public health, but stated that FDA would take any necessary steps to act in this matter. He also announced that FDA planned on conducting a nation-wide survey of packaged foods in order to determine the amount of PCB's in packaging materials and in the foods within the contaminated packages. This packaged food survey, which was conducted during the fall and early winter months, yielded additional findings of PCB's in paper and paper-board packaging, and also examples of PCB's in the food — which were presumed to have migrated from the packaging.

On March 18, 1972, FDA published its proposed rule-making on polychlorinated biphenyls. In the prologue of this regulation they reported on the results of the packaged food survey and noted again that the toxicological affects of PCB's were limited and that there was no immediate hazard to the public health. Nevertheless, they felt that the levels of PCB's in food for human and animal use should be significantly reduced and proposed temporary tolerances on certain specific types of foods, ranging from 1/10 of a part per million

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to 5 parts per million. They also established a temporary tolerance of 5 parts per million on food packaging materials. Sixty days were allowed for comments on this proposed rule making, which was later extended to 120 days.

In meetings with FDA officials following the publication of this proposed rule making, it developed that in referring to a "temporary" tolerance, they meant that -- whereas it was 5 parts per million now -- in a year or so it might be reduced to 2 parts per million and eventually to 0.

On March 29, at a meeting of API's B&CR Committee, under the Chairmanship of Paul Cundy of the American Can Company, it was determined that the paper industry should file comments on this FDA proposal. A suggestion was made that special legal counsel be retained to assist in the preparation of the industry's brief.

On April 20, representatives from the legal subcommittee of the B&CR Committee met in Washington

-- along with API's regular counsel -- to interview four candidate law firms. Their recommendation -- which was approved by API's Executive Committee -- was that Miss Selma Levine of Wald, Harkrader & Ross be retained. Miss Levine has extensive experience in cases involving the Food and Drug Administration.

The PCB task force, an ad hoc subcommittee of the B&CR Committee, which under the Chairmanship of Paul Trout of Container Corporation had been working on the PCB problem with FDA, met with Selma Levine on April 24 to determine the paper industry's strategy in preparing comments on the proposed regulation.

It was decided that it would be most helpful to have an independent and credible assessment of the economic impact of this proposed FDA regulation on the recycled paperboard segment of the paper industry. The firm of Arthur D. Little in Cambridge, Massachusetts, was retained to do the study. ADL was familiar with the paper industry and had just completed a study for the federal government on the economic impact of pollution control for various segments of the industry.

The PCB task force spent a busy spring: meeting regularly with our special Washington counsel — and from time to time with Arthur D. Little, and on the 7th of July, the full B&CR Committee met in Washington to review a draft of the brief which our Washington counsel had prepared, responding to FDA's proposed regulation.

Following this, on July 17, the comments of the American Paper Institute in the matter of polychlorinated biphenyls were filed with the Hearing Clerk at HEW.

What did we say? Our comments covered some 54 pages — not including 5 lengthy exhibits. So, I will not try to do anything more than hit the high spots. Our position was basically that, while we were in full accord with reducing the levels of PCB in the food supply, we did not believe that establishing a tolerance on PCB's in food packaging materials would accomplish this. We felt, in short, that tolerances should be imposed on the foods. We pointed out that the rule making would require testing of all packaging materials even though present test procedures are too inaccurate to insure compliance

at a 5 parts per million level.

The added costs resulting from this testing would be imposed at both virgin and recycling mills, however we showed that the major cost impact would fall on combination paperboard mills, which are economically one of the weaker sectors of the paper industry.

We cited the Arthur D. Little study which projected that, at a minimum, this regulation would cause by the end of 1974 the closing of 5 to 9 recycling mills. This, we indicated, was not in the public interest inasmuch as such shutdowns would entail adverse environmental, economic and social consequences.

We commented on the unreliability of the test procedure and the variations in test results on the same samples between different labs.

Quoting the Hazelton study on effective barriers, as well as other authorities, we pointed out that the proposed rule failed to take into account the protection against PCB migration afforded by such factors as barrier materials, the nature of the food being packaged, and the package-weight to food-weight ratio.

We further pointed out that Aroclor 1242 — the PCB found in recycled paperboard — is the least chlorinated form of PCB found in the environment, and there is no evidence to indicate that Aroclor 1242 either persists or accumulates in the environment ... and so becomes a toxicological hazard to man. Moreover, Aroclor 1242 has over the years comprised the largest share of domestic PCB production, so it should be the most widely found PCB in the environment. This, however, is not the case.

API was not the only one to comment on this rule making. Many companies and other associations within the paper and paper-packaging industries filed comments. One of the officials at FDA told us they were overwhelmed at the degree of response.

For the balance of the summer and the fall, aside from a few informal conversations between FDA personnel and our counsel in Washington, nothing of any great significance happened until, on December 21, 1972, FDA published their Final Environmental Impact Statement. Under the National Environmental Policy Act, all governmental

agencies are required to file an environmental impact statement whenever any of their administrative actions could have impact on the environment. The FEIS (Final Environmental Impact Statement) indicated that FDA plans to make three major changes in its rule making. First, that now the tolerance would not be on all food packaging materials as in the original proposed regulation, but would be limited to paper food packaging material.

Second, that the temporary tolerance of 5 parts per million on food packaging materials is to be raised to a temporary tolerance of 10 parts per million and,

Third, that they recognize functional barriers.

However, this latter change was qualified by saying that such barriers must be "impermeable to PCB's." Further discussions with FDA indicated that the only items they would now consider "impermeable" were glass, metal and foil.

It was the opinion of our counsel that the FEIS was — and I quote -- "grossly deficient." It was inadequate because there was no evaluation of the environmental results of adopting a 10 ppm tolerance. Moreover, alternatives to the proposed regulation were not mentioned and accordingly their environmental impact was never weighed.

Also, the FEIS did not discuss the environmental impact of the possible removal by other Washington agencies of carbonless copy paper from inventories. API's comments on the FEIS were filed on January 22.

What is the situation now and what are our plans? Currently we understand that FDA is preparing a supplement to its Final Environmental Impact Statement, and is also working on the final rule making. There seems to be some question as to whether they plan to publish these together or will first issue the supplement to the FEIS and follow up at a later date with the proposed rule making. In either case, once the rule making is published, we have the option of requesting a hearing — which would then give us an automatic stay of the rule making. If FDA should turn us down on such a request — which our Washington counsel feels is likely — the industry will then

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have to decide whether it wishes to go to the Appellate Court and request them to direct FDA to hold a hearing on the PCB rule making.

While we are waiting for FDA to act, we are presently preparing a letter suggesting that FDA update some of the information on which the original proposed rule making was based. The packaged food survey, which FDA conducted in the fall of 1971, was based on samples collected during the summer of that year. At that time the waste stream was heavily contaminated with NCR papers and the paper industry had not instituted the strong quality control measures with regard to paper stock, which now exist at combination paperboard mills.

We have taken one other step. We have contracted with Arthur D. Little again to survey the recycled paperboard industry to determine what the actual economic impact will be with the 10 part per million tolerance. This study, which is currently underway, should be completed around the first of April.

Up to now, this has all been somewhat theoretical. We have been dealing with a proposed regulation. Moreover, no testing or sampling procedure, as yet, has been even suggested by FDA. But, when you consider that the price of paperboard is around $150 per ton and the cost of each test for PCB is about $30, you can see the potential economic impact to recycled paperboard mills. Also, keep in mind that the food packager has only one thought, he does not want to see headlines about PCB's and his product. Therefore, he will insist on a guarantee that the packaging material he buys is under the tolerance.

So, we begin to see that, although FDA has stated again and again that PCB's represent no immediate hazard to the public health, and although there is no evidence that Aroclor 1242 — the PCB under question — accumulates in human tissue, FDA proposes to "solve" a problem that they, in effect, admit may not exist, by placing a further economic burden on a segment of our industry which already suffers from marginal profitability.

Will the environmental, the economic and the social losses resulting from this proposed action be outweighed by a questionable protection of the public health? On the contrary, the paper industry believes that this is but another example of, "a little learning is a dangerous thing..."

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