W.B. Papageorge (DO NOT TYPE). cc. TLG
Dr G. Roush.

Hazleton Laboratories

DR THOMAS ELLIOTT of Dept of MICROBIOLOGY
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Called 9/8/75 to request samples of AROCLOR 1254 to carry out MUTAGENICITY testing on liver cells

I advised Dr Elliott of our sample procedure and arranged for Peggy to send them forms.

MONS 028790

PCB REGULATORY ACTION SEEMS TO BE PERPLEXING TO THE EPA

Regulation of polychlorinated biphenyls (PCBs) seems to be confounding the Environmental Protection Agency. Available regulatory options, separately or simultaneously, do not seem to produce an entirely satisfactory answer in view of the extent and levels of PCB contamination and the numbers and types of adverse effects of PCB.

Without the Toxic Substances Control Act, EPA says it cannot ban PCBs. If it passes:

The agency's maximum control position would limit PCBs to two uses: transformers and large capacitors.

A less stringent regulatory policy would limit PCBs to uses in closed systems, including transformers, capacitors, heat transfer systems, hydraulic equipment, and vacuum pumps.

In closed systems, PCBs are recoverable, since, in use, PCBs are not generally dispersed into the environment.

Another regulatory option calls for encouraging a gradual end to all PCB uses or those for which there are acceptable substitutes. EPA knows of two possible PCB substitutes.

In any event, the agency will probably issue a final PCB water quality criteria level of 1 p.p.t. This would apply to all industrial effluents. EPA had originally considered a 10 p.p.t. criteria sufficient.

EPA is also considering moving against PCBs in water effluent discharges on a case-by-case basis under the Federal Water Pollution Control Act.

An EPA official noted that banning PCBs in water effluent would not solve the problem since PCBs are ubiquitous, are used in numerous things and do pose a disposal problem.

Some EPA officials would like the agency to hold off on any PCB regulatory action until Congress returns next month. They reason that the PCB issue could be used to stimulate favorable early action on the Toxic Substances Control Act (See July 23, Pages 28 and 29).

In supporting this legislation, EPA has repeatedly maintained that PCBs should never have been in the environment in the first place.

EPA's PCB Regulatory Position May Be Released Next Week

There is a good chance the agency will announce its position on PCB regulation at Wisconsin's Aug. 27 and 28 hearings on limiting PCB uses. Other States are also considering PCB use limits.

A number of PCB adverse human and animal health effects have been known for some time.

But, it is understood that EPA has or is about to get a report on animal studies demonstrating PCB carcinogenicity.

In addition to the above PCB regulatory possibilities, other current EPA activities include:

-- Development of control technology to remove PCBs from effluent discharge. The agency plans to negotiate a contract with Chemico Process Plants Co., Envirogenics Systems for chemical techniques for removal of PCBs from water.

-- The National Academy of Sciences has been asked to consider whether a PCB drinking water standard is needed. Monitoring of PCBs in drinking water has been expanded.

-- PCB manufacturers, users and importers have been asked for use and distribution information and for data on the levels of PCBs in effluent discharge at manufacturing plants.

-- Adipose tissue sample collection and analysis for PCBs is continuing.

-- Dow Chemical Company has been requested to file test data on the chemical properties and potential bioactivity of its PCB substitutes.

-- Analyses of the technological and cost aspects of using substitutes for PCBs in closed electrical systems are underway.

-- Mandatory guidelines for PCB disposal by federal facilities "may" be prepared under the Solid Waste Disposal Act.

EPA is aware of two PCB substitutes. According to the agency, "Dow Chemical has developed a product for use in large power capicitors, and Dow Corning has a product which can substitute for PCBs in certain transformer applications. These substitutes are reportedly being introduced at the present time in Japan."

EPA's Office of Toxic Substances (OTS) has noted in a draft memo that "While Monsanto is believed to be limiting its sales to manufacturers of closed electrical systems, PCB reprocessors are known to be selling for other uses. Most of the PCB imports (which exceeded 175,000 pounds in 1974 are not used in closed electrical systems. Among the PCB uses which are known to persist in the U. S. at present are applications in investment casting processes, heat exchange fluids, and hydraulic fluids. There are a variety of other potential uses of PCBs although firm evidence of such current uses is not in hand."

A few years ago, the Food and Drug Administration set several tolerances for PCBs in food and limited PCB contamination in food plants and packaging. The tolerances range from .2 p.p.m. in baby food to 5 p.p.m. in fish.

The OTS draft memo noted that the FDA actions caused PCB levels in food to decline steadily. But, OTS said, PCB levels in fish and wildlife appear to have increased. The draft memo stated:

> "Unusually high levels of PCBs have been detected in recent months in the fish in Lake Michigan (up to 165 p.p.m.), Lake Pepin (up to 40 p.p.m.), the Hudson River (up to 350 p.p.m.), and Southern California (up to 6.6 p.p.m.). PCBs have been detected in sludge from sewage treatment plants as well as in the effluents from these plants. PCBs have been identified in only two drinking water supplies during the past year.
>
> "There have been five water spills involving PCBs during the past year."

In the memo, OTS noted recent research results on the adverse health and ecological effects of PCBs. According to the draft memo, "concentrations as low as 2.5 and 5 p.p.m. have produced serious adverse health effects in monkeys, including loss of hair, acneform lesions, loss of weight, increased secretion of total urinary ketosteroids, irregularities in menstraul cycles, impaired ability to maintain pregnancy, and undersized offspring ... Several superficial reports of chloroacne among workers exposed to PCBs have been received. Also, concentrations of 5 p.p.m. in fish eggs have resulted in fry mortality."

A draft of a July, 1975 report, "State of Concerns of the Lake Michigan Toxic Substances Committee Related to Polychlorinated Biphenyls," listed adverse effects of PCBs. The report, prepared by federal and state agency officials, stated that it did not constitute EPA policy. The draft listed 19 previously known PCB biological and toxicological effects. These included:

-- "Teratogenic effect in chick embryo."

-- "Acute oral LD_{50} in mammals varies from approximately 2-10 gm/kg. (Apparent increase in mammalian toxicity with decrease in chlorine content)."

-- "Generally enzyme induction increase with increase in chlorination of PCBs."

-- "Enlargement of the liver and vacuolar or fatty degeneration of liver cells in rats, guinea pigs and monkeys."

-- "Production of hydropericardial edema in chickens and Japanese quail."

-- "Adverse reproductive effects in rats at levels of ca. 100 p.p.m. in diet."

-- "Adverse reproductive effects in mink."

-- "Effects on hatchability in chickens, Japanese quail."

-- "Skin, liver and kidney lesions in rabbits following dermal exposure."

-- "Chloracnegenic and hepatotoxic effects in man."

-- "Hyperglyceridemic effects in man."

-- "Human miscarriages, still births and transplacental transmission in abnormal pigmentation from 'rice-oil disease' ('Yusho')."

-- "Chloracnegenic effects of chlorinated naphthalene contaminants in man."

It appears there is sufficient evidence for PCB regulatory action. Beside FDA tolerance action on PCBs, the Lake Michigan Toxic Substances Committee last month recommended a partial PCB ban.

The Committee noted that "past and more recent data demonstrate that loss of PCBs to the environment constitute an environmental and human health hazard and are a direct cause of economic loss to the commercial fishery." Committee conclusions included:

-- "The effect level of PCBs in primates reproductions is recently documented as less than 2.5 p.p.m. and is much lower than has been observed in Standard test mammals (rats)."

-- FDA is enforcing the 5 p.p.m. PCB tolerance for fish.

-- PCB concentrations in Lake Michigan fish exceed the 5 p.p.m. tolerance.

-- Restrictions on PCB discharges from manufacturing plants have not reduced PCB levels in the Lake.

-- "The presence of PCBs in many processes and products continues to be widespread in spite of Monsanto Chemical Company policy to restrict sale to closed systems."

-- "For many uses, PCBs can be eliminated or replaced by alternative chemicals."

Based on these and other conclusions and concerns, the Committee recommended "a national ban on all domestic and imported PCBs destined for use other than in transformers and capacitors and that the critical or essential use of PCBs in transformers and capacitors be immediately and critically reviewed in light of current potential replacement products."

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TWO CONTRACTS TO STUDY PESTICIDES LET BY U. S. ARMY

Two contracts for study in the pesticide field have been let by the U. S. Army Research and Development Command. A $58,039 contract to study sylvatic plague and evaluate systemic insecticides for control of the fleas in wild rodents was signed with the Health and Social Services Department of the State of New Mexico, Santa Fe.

The second contract, for $29,654, was let to Stanford Research Institute, Menlo Park, Ca. for the development of mosquito repellents with increased protection time in man.

The Environmental Protection Agency has announced its intention to negotiate a contract for the development and implementation of vocational agriculture training programs for future farmers, young farmers and adult farmers who need certification as posticide applicators with Ellis Associates, Hyattsville, Md.

The agency has also issued a request for proposal on a contract to conduct bioassay on several aquatic species with a variety of chemical toxicants.

A contract to study the long range toxicological effects of specific fungicides has been negotiated for $48,500 between the National Institutes of Health and the Midwest Research Institute, Kansas City, Mo.

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EPA ISSUES FORMAL RECALL ON WATER PURIFIER PRODUCT

The Environmental Protection Agency's Region IV office has issued a formal recall request to Water Purification Technology, Inc., Miami, Fla. The recall involved the product, The Purewater Maker, which officials said was misbranded and not registered.

Region IV has also issued a Stop Sale, Use or Removal Order to Triangle Chemical Company of Macon, Ga., for the product Triangle Super-Duper 6-2-1, which was misbranded.

Two Substantial Civil Penalties Issued in EPA Regions

In other recent regional action, a $2,484 civil penalty was issued in Region VI to Chemtech Industries, Inc., Dallas, Tex. The complaint was based on the firm's holding for distribution or sale the products, Algae-Out and Ward-Off, which were allegedly misbranded and adulterated.

Another civil penalty in the amount of $2,240 was agreed to in Region X by Nulife Fertilizer Division, Hygrade Food Products Corporation.

The complaint against the Tacoma, Wash., firm was based on its holding for distribution or sale the product, Nulife Weed and Feed, which was allegedly misbranded and adulterated.

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PEPS II SET FOR FEDERAL REGISTER PUBLICATION SOON; EFFICACY REQUIREMENT IN

The Environmental Protection Agency is readying its Pesticide Enforcement Policy Statement (PEPS) on Structural Pest Control for final Federal Register publication possible as early as next week. Little different than the most recently circulated