Monsanto

FROM (NAME & LOCATION): Medical Department

DATE: April 5, 1971

SUBJECT: Mention of PCB's in papers at ACS Meeting

REFERENCE:

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Attached are several pages from this weeks Food Chemical News with mention of environmental pollutants in food as discussed by FDA personnel.

PCB's were mentioned on several occasions. One of particular interest may be the papers described on "page 22" identified by the red ink.

Elmer P. Wheeler

EPW/bks

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The law students were organized in seven groups to testify on specific consumer issues before Kennedy's subcommittee. The groups were established in a course taught by John F. Banzhaf, III.

Supporting the Kennedy-sponsored legislation, the students charged that "consumer problems are not adequately faced or promptly resolved by the Federal Government because archaic procedures, stultifying red tape, bureaucratic inertia, and industry influence predominate in administrative and regulatory agencies."

Kennedy commented that "too many decisions are made within the vast bureaucracy," without consumers having the opportunity or resources to challenge the agency decisions.

FDA ER STRESSES ENVIRONMENTAL POLLUTANTS IN FOOD

Food and Drug Administration increased attention to environmental contaminants in food was emphasized at last week's American Chemical Society meeting in Los Angeles in a speech by Dr. Virgil O. Wodicka, director of the agency's Bureau of Foods. Wodicka's speech was delivered by FDA's Alan T. Spiher, Jr.

Noting confusion surrounding FDA's "administrative guidelines" for levels of environmental contaminants in specific foods, as opposed to the formally-established tolerances, Wodicka wrote:

> "In the case of a published tolerance, the user of an additive may appropriately set his target at any value that offers satisfactory probability that the tolerance value will not be exceeded. In the case of the additives covered by guidelines, the only appropriate target is zero. The guidelines represent an administrative recognition that, as a practical fact of life, the target value of zero is unobtainable; but also that as long as the guideline value is not exceeded, there is not an important hazard to the public health."

When a substance is identified as a possible health hazard, Spiher said, the formal tolerance-setting procedure is too cumbersome to be satisfactory "as a control measure." He conceded that setting an administrative guideline is "more arbitrary in that it is a straightforward administrative procedure and does not involve public participation in the procedure," but he said that "the decisions so made are still subject to challenge in the courts by any party who feels himself aggrieved."

The Wodicka speech described environmental contaminants as "indirect additives." He said that "FDA is considerably stepping up its investigative processes to identify a broader spectrum of environmental contributions to the food supply in the form of indirect additives and to study the consequences of their presence when found."

The speech noted that, "Opening the consideration of indirect food additives has much in common with opening Pandora's box." Wodicka wrote that the problem is complicated by "the fact that the chemical constituting the problem in the food supply might be quite different from the pesticide applied to the raw agricultural commodity or the industrial chemical that found its way into the environment after discharge." Wodicka noted problems of chlorinated dioxins resulting from use of 2,4,5-T, polychlorinated di-benzofurans resulting from use of polychlorinated biphenyls and methyl mercury resulting from discharge of mercury as metal or inorganic salt.

Implications of such "indirect additives" have "more widespread application to the chemical industry than has been generally realized," Wodicka wrote. Noting the proposed legislation to give the Environmental Protection Agency control over introduction of new chemicals, Wodicka wrote:

> "With today's sensitive analytical methods, it is now possible to identify in foods, in water, and in fact, in people, trace quantities of substances which nobody would dream of consciously adding to any of the three. With our present state of knowledge, there is seldom sufficient information to know whether we in the affected industries and the regulatory agencies should view with alarm this developing situation, but certainly there is no reason to think that any of us should point with pride.
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> " . . . much more information is needed to determine whether there should be more stringent controls on some of these substances, or whether, in fact, they should be avoided completely because in the absence of evidence establishing safety, there will unquestionably be increasing public demand for restriction of methods of use and disposal to those which preclude contamination of food, water, and the environment generally."

The most widely-publicized paper delivered at ACS concerned hexachlorophene. Dr. August Curley, of EPA's Chamblee, Ga., laboratory, reported on the tests. Although the hexachlorophene paper was widely discussed prior to the meeting and was widely publicized during the meeting, the paper by Curley and Dr. Robert T. Hawk dealt mainly with analytical methodology. At a news conference in Los Angeles, Curley was reluctant to be quoted.

The EPA work showed that high levels of hexachlorophene experimentally caused brain lesions in rats, and that human tests showed absorption through the skin and levels in the blood of human volunteers ranging from 1 p.p.b. to 89 p.p.b. EPA noted that hexachlorophene, in addition to its use as a disinfectant, has been recommended for agricultural use as a fungicide and bacteriocide.

FDA-ers, asked about the Curley work, said last week they are looking into the situation, particularly with regard to routine use of hexachlorophene on newborn infants and use in products which contact mucuous membranes.

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Curley also delivered a paper on polychlorinated biphenyls, showing PCB storage in fatty tissues at higher levels than have been found for DDT residues in rat feeding studies. The EPA scientist reported that, "if a steady state does exist for PCB storage in rats, it far exceeds the four month estimate as the time required to reach a steady state with DDT."

Papers Deal with PCB's, Dioxins

Another EPA paper, this one on testing in human subjects for pollutant burdens, said the agency will assay PCB and chlorinated hydrocarbon pesticide residues in plasma samples from 800 volunteers. Another EPA test will involve assaying selected trace elements and PCBs in samples of hair collected from members of 1,500 families with varying exposure to urban air pollution. Yet another EPA study will assay PCBs in fat collected during elective surgery on residents living along a river system that may provide a PCB exposure gradient.

Dr. Helene C. Cecils, of the Agriculture Department's Agricultural Research Service, reported PCB feeding tests in rats, saying that PCBs induced a decrease in liver vitamin A. This effect, she said, is similar to that of DDT, when each is fed at 100 p.p.m.

A paper presented by scientists of the State University of New York at Buffalo reported mercury over FDA's 0.5 p.p.m. guideline level in commercially important fish in western and central Lake Erie, as well as mercury in plankton and algae at the mouth of the Buffalo River. Dr. K.K.S. Pillay said mercury was found in edible portions of walleyed pike ranging from 0.3 p.p.m. to 0.8 p.p.m. Cohoe salmon tested had mercury ranging from 0.5 p.p m. to 0.7 p.p.m.

A number of papers at ACS dealt with the problem of dioxins. Dr. Jack R. Plimmer, of ARS, tested 2,4-D and 2,4,5-T to see if action by sunlight forms dioxins under natural conditions in the environment. He said his findings indicated that it is "unlikely" that the pesticides "can form dioxins under natural conditions . . ."

Another ARS paper showed that no adverse effects in soils from dioxins have been demonstrated. Dr. Philip C. Kearney said that from 80% to 85% of TCDD applied to soil was recovered in sampling, indicating that the dioxin is persistent. He also said that incubation of 2,4-D and 2,4,5-T in soils produced no dioxins, adding: "Thus, I think it very unlikely that dioxins could be produced in nature from either of the two pesticides."

ARS's Dr. Edwin A. Woolson described a new method to detect dioxins in chlorinated compounds. He said the electron-capture gas-chromatographic procedure can detect 0.1 p.p.m. of dioxins.

Dr. Donald E. Clark, another ARS scientist, checked residues of chlorophenoxy acid herbicides in cattle and sheep. ARS fed silvex, 2,4,5-T, or 2,4-D at levels from 300 p.p.m. to 2,000 p.p.m. daily for 28 days. The animals were slaughtered either within 24 hours of the final feeding or after a 7-day withdrawal period. Clark reported that residues in muscle did not exceed 2.0 p.p.m. of silvex, 2.7 p.p.m. of 2,4,5-T, and 0.10 p.p.m. of 2,4-D in animals slaughtered within 24 hours of the final feeding.

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A paper by USDA's Crops Research Division reported that current production of phenoxy herbicides holds TCDD content at less than 0.5 microgram per gram. The scientists studied 129 samples of 18 pesticides derived from chlorophenols. Of the samples, 76% contained 2,3,7,8-tetrachlorodibenzo-p-dioxin at less than 0.1 microgram per gram, 7% between 0.1 and 1.0, and 9% at a level greater than 1.0.

Scientists of the Environmental Research Group in Michigan reported high levels of selenium found in zooplankton in Lake Michigan directly downwind from Chicago, and, to a lesser extent, from Milwaukee. Dr. Richard A. Copeland said selenium was found at from 0.1 p.p.m. to 1.2 p.p.m. in zooplankton throughout the lake, noting that the U.S. Public Health Service tolerance for selenium in drinking water is 0.01 p.p.m.

Scientists from St. Mary's College reported on tests of DDT in Drosphelia pseudo-obscura, saying that the insecticide "had the evolutionary effect of causing shifts in the genetic content of populations" of the specie of fruitfly. An ARS study on DDT in laying hens showed no change in eggshell thickness.

The University of Washington's College of Forest Resources reported on chemically imprisoning pesticides in solid waste macromolecules, such as the lignocellulosic materials bark, sawdust, and lignin. Dr. C. S. Chopra said combining a pesticide with a solid waste can result in a controlled release form.

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MERGER OF FOOD REGULATION IN FDA URGED BY CHOATE

"Food inspections and standards and grades must be consolidated," consumer advocate Robert B. Choate said March 29 at a Food Update conference in San Diego, Calif., adding: "A trustworthy Food and Drug Administration would seem a better place for these functions than today's Department of Agriculture."

However, Choate, representing the Council on Children, Media and Merchandise, said, "To earn that 'trustworthiness,' FDA would have to develop a more honest consumer policy."

At the meeting, sponsored by the Food and Drug Law Institute, Choate mounted his most violent attack against FDA, specifically criticizing Commissioner Edwards, Deputy Commissioner Grant, General Counsel Goodrich, and Food Bureau Director Wodicka.

His pitch to industry was that, "You have need for an outside force to enable you all to reform together." Choate said industry would fare better with strong regulatory agencies than it would under continuing fire from laymen seeking to represent the consumer.

Regarding FDA, Choate urged industry: MONS 098336

> "If you are interested in saving face, it should be logical for you to use the excuse of government-enforced corrections to clean up your own shop. If you didn't spend so