Regarding reproduction, the letter noted Russian work indicating "increased fetal death in rats fed low levels . . ." The Group said that "FDA finally initiated studies to test the effect of FD&C Red No. 2 on reproduction," adding:

> "Although these studies on reproduction are not yet completed, there is evidence that the findings thus far give credence to the Russian study and raise serious questions about the safety of FD&C Red No. 2. Recent statements by FDA and industry officials suggest that this is the case."

Nader's Health Research Group also commented:

> "The amount of time it took for FDA personnel to become aware of the Russian studies of the effects of FD&C Red No. 2 on reproduction underscores the FDA's lack of aggressiveness. Nearly a year passed before the FDA became aware of the Russian reproductive study published in March-April 1970. Moreover it was the Allied Chemical Corporation - - not the agency's own scientists - - who brought FDA's attention to the article. Allied Chemical . . . translated the Russian article into English for the FDA. This act of 'public service,' however may not be as selfless as it appears. Allied Chemical Corp. is a major producer of FD&C Red No. 40 . . ."

Russian work on possible carcinogenicity was also noted by Nader and his colleagues, who said, "This study has been criticized on several grounds and, thus, uncertainty exists as to whether or not FD&C Red No. 2 can cause cancer."

"Rather than pursue this serious question to its scientifically acceptable resolution;" the letter said, "the FDA has chosen to 'close' the issue of carcinogenicity by not conducting further studies."

In the letter, Nader also continued his fight against Citrus Red No. 2, about which he corresponded with Edwards earlier this year (See FOOD CHEMICAL NEWS, Jan. 11, Page 18).

WODICKA REPORTS PRELIMINARY FINDINGS OF PCB STUDY

In a preliminary progress report on the Food and Drug Administration's survey of polychlorinated biphenyls in food and food packaging, Dr. Virgil O. Wodicka, Director of the Bureau of Foods, reported that the agency was finding PCBs frequently in fish, only on occasion in eggs, poultry, and milk, and when detected in dry foods products it is almost always as a result of migration from packaging (See FOOD CHEMICAL NEWS, Nov. 1, Page 2).

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Wodicka summarized results both from the agency's special survey for PCBs in 15 food commodities (See FOOD CHEMICAL NEWS, Oct. 4, Page 3), and from FDA's Market Basket studies, which also are used to determine the extent of pesticides found in the U.S. food supply.

He said the results of the special study, which were presented in chart form at a PCB Workshop, sponsored by the Grocery Manufacturers of America Nov. 17, were still too preliminary to draw conclusions from, and the FDA's followup actions will be based on analysis of the findings. He speculated that it would be a few more weeks before any interpretation of the results can be made. In his general summary, Wodicka also noted that no PCBs had been found in fresh fruits or vegetables.

Turning to the special survey, the FDA-er presented results from 584 samples, representing products of 464 firms, which had been tested for PCBs from 12 of the 17 participating Districts. He said results from the five other Districts were expected by the end of the month.

Only 28 samples of food showed PCBs residues, according to the charts presented by Wodicka, at 0.5 p.p.m. or greater in non-fatty foods, and at 1.5 p.p.m. or greater in fatty foods. The survey results were presented for foods packaged in grayboard and other cardboards, and included results of analysis for the food, the box or carton, inner wrapper, dividers, outer wrapper, and other cartons, including the shipping carton. In all cases, Wodicka presented the number of samples taken in each category, and the range of PCB finding for each category and the mean of the results.

For food packaged in grayboard, the following were the ranges and mean levels:

(1) Crackers, bread crumbs, etc. - - trace amounts to 0.45 p.p.m., with a mean of 0.04 p.p.m.; (2) Macaroni and noodle products - - zero to 0.6 p.p.m., mean of 0.03 p.p.m.; (3) Pretzels, chips, etc. - - trace to 1.4 p.p.m., mean of 0.2 p.p.m.; (4) Breakfast cereals, ready-to-eat - - trace to 3.7 p.p.m., mean of 0.2 p.p.m.; (5) Prepared mixes, dry - - trace to 3.0 p.p.m., mean of 0.1 p.p.m.; (6) Dried milk and dried milk products - - zero to 0.22 p.p.m., mean of 0.05 p.p.m.; (7) Dessert and pudding mixes - - trace to 0.2 p.p.m., mean of 0.02 p.p.m.; (8) Infant cereals, dry - - trace to 1.0 p.p.m., mean of 0.3 p.p.m.; (9) Cookies, ready-to-eat - - trace to 11.8 p.p.m., mean of 0.4 p.p.m.; (10) Refrigerated, unbaked bakery specialties - - zero to 0.1 p.p.m., mean of 0.0005 p.p.m.; (11) Rice, oatmeal, and farina - - trace to 1.2 p.p.m., mean of 0.1 p.p.m.; (12) Chocolate and cocoa products - - trace to 0.52 p.p.m., mean of 0.02 p.p.m.; (13) Grated cheeses and cheese products, dry - - none found; (14) Dried fruits - - trace to 0.1 p.p.m., mean of 0.01 p.p.m.; and (15) Frozen fruit juices - - none found.

The following were the ranges and mean level for food packaged in in other cardboards:

(1) Crackers, bread crumbs, etc. - - zero to 0.4 p.p.m., mean of 0.04 p.p.m.; (2) Macaroni and noodle products - - trace amounts to 0.1 p.p.m., mean of 0.04 p.p.m.; (3) Pretzels, chips, etc. - - zero to 0.3 p.p.m., mean of 0.03 p.p.m.; (4) Breakfast cereals, ready-to-eat - - zero to 0.2 p.p.m., mean of 0.02 p.p.m.; (5) Prepared mixes, dry - - zero to 2.7 p.p.m., mean of 0.25 p.p.m.; (6) Dried milk and dried milk products - - none found; (7) Dessert and pudding mixes - - trace amounts to 2.5 p.p.m., mean of 0.2 p.p.m.; (8) Infant cereals, dry - - zero to trace amounts, mean of zero; (9) Cookies, ready-to-eat - - trace amounts to 10.0 p.p.m., mean of 0.4 p.p.m.; (10) Refrigerated, unbaked bakery specialties - - zero to trace amounts, mean of zero; (11) Rice, oatmeal,

arina - - zero to 2.3 p.p.m., mean of 0.6 p.p.m.; (12) Chocolate and cocoa products - - race amounts to 0.4 p.p.m., mean of 0.04 p.p.m.; (13) Grated cheeses and cheese products, dy - - none found; (14) Dried fruits - - zero to 0.1 p.p.m., mean of 0.02 p.p.m.; and (15) Frozen fruit juices - - none found.

(Trace amounts were not included in the calculations to determine mean levels.)

The ranges and mean levels of the PCBs found in cartons, inner wrappers, dividers, outer wrappers, and shipping containers were at much higher levels, but varied from product-to-product, indicating a problem for the packaging industry until steps are taken to insure a relative absence of PCBs from paper used for food packaging (See following story).

Wodicka reported that a survey of PCBs in animal feeds will follow the completion of the packaging survey.

During the question period, Wodicka generalized that findings in foods, if the product was of animal origin, usually meant that the PCBs came from the food itself. However, if the product was of plant origin, he speculated that it probably came from the package.

He also noted FDA was not sure of the process of the PCB migration, but this was being studied.

BLUMENTHAL DESCRIBES PCB'S AS "POTENTLY TOXIC" TO HUMANS

Dr. Herbert Blumenthal, Acting Deputy Director of the Division of Toxicology of the Food and Drug Administration's Bureau of Foods, last week characterized polychlorinated biphenyls as "potently toxic" chemicals to humans.

Blumenthal reported to a Workshop on PCBs, sponsored by the Grocery Manufacturers of America, on his recent trip to Japan to investigate the so-called "Yusha" incident of 1968 in which 1,001 cases of poisonings from PCBs were documented from rice oil accidentally contaminated with PCBs (See FOOD CHEMICAL NEWS, Nov. 1, Page 2).

The studies conducted by Kyushu University, Fukuoka, Japan, according to Blumenthal, showed that the poisonings did not discriminate by sex or age.

Of the 1,001 cases, 502 involved males and 499 females, and the poisonings were evenly distributed through most age brackets, with a slightly lower number among the over 60 age group, he said.

The victims ate oil with PCBs at levels between 2,000 and 2,500 p.p.m., and exhibited symptoms of acne and other skin rashes on the body, a form of karatosis on the hands and soles of the feet, swelling of the joints, pigment under the nails, discoloration of the mucuous membrane, swelling of the eye lids accompanied by a discharge, anorexia, nausea, headaches, and muscle weakness, among others.

Most of the poisoning victims are still being treated, he told the meeting.

Of 10 births to women who ate the contaminated oils, eight were live, and the two deaths could not be related to PCBs in any way.

The other infants were born with a discoloration of the skin, and some had a form of dermatitis that disappeared in about three months. He noted that physicians did not allow the infants to nurse from their mothers.

Examinations three years after birth, Blumenthal said, showed that the youngsters were apparently normal in every respect.

The prognosis for the adults, he indicated, is not as good, pointing out that some of the acne-type disorders are improving, but the muscle weakness had not diminished to any great degree.

He also listed a number of clinical findings, emphasizing that the most disturbing was the increase in serum triglycerides.

In summary, he told the meeting that poisoning victims had exhibited a wide spectrum of symptoms, some of which have been irreversible, and still showed PCBs stored in the body fat some three years from the poisoning that occurred in the period of June-to-October of 1968. Blumenthal said the incident underscores the need "to exercise conservatism" in FDA's approach to food products contaminated with PCBs.

During the meeting, Elmer P. Wheeler, Monsanto's Manager of Environmental Health, reviewed preliminary results from two-year rat and dog studies on PCB toxicity, presented earlier in the year at the Society of Toxicology meeting (See FOOD CHEMICAL NEWS, March 15, Page 6). Final results from the work of Industrial Bio-Test Laboratories, he said, are now being studied, but he did not believe that any significant changes would be uncovered from the earlier work that showed adverse effects from high level feeding of PCBs to animals.

Herbert H. Cornish, Professor of Environmental and Industrial Health in the School of Public Health at the University of Michigan, summarized PCB studies from the literature, and concluded that liver damage occurs at high levels of feeding. He enumerated a long list of further work required on PCBs, emphasizing the need to study effects of the chemical on the microsomal enzyme systems of the liver, which Cornish said have shown some adverse effects from PCBs, along with work on heme synthesis.

Cornish noted that even with improved controls to eliminate PCBs from packaging, which is the current concern of FDA and others, much work needs to be done because of the world wide distribution and contamination of fish and wildlife by PCBs. He listed PCB findings in a number of animal species from other countries.

Trout Describes Demands Made by Food Firms on Packagers MCNS 069903

Paul E. Trout, Director of Environmental Control for the Container Corporation of America, described the work the American Paper Institute is sponsoring at Hazleton

Laboratories (See FOOD CHEMICAL NEWS, Nov. 8, Page 16) and the Institute of Paper Chemistry to examine the problem of paper contamination, and to improve methodology to institute better controls.

Trout told the meeting that he didn't believe there was a health hazard from PCB contamination in the amounts being found, and he predicted that levels will decrease because of the steps being taken.

He noted that the use of the major contributor to the levels, PCBs from "carbonless" carbon paper, had been discontinued, but it would take time before all of this disappeared.

Trout expressed concern over some of the specifications that food manufacturers were requiring in food packaging orders, including warranties that the products were free of PCBs, or reports of analyses of all PCBs found in the packaging.

One of the problems encountered by the paper industry, he explained, was the differences in analyses that companies were getting from commercial laboratories who were examining paper products. He pointed out that many of the paper companies were not prepared to undertake the tests in their own laboratories when the problem was first uncovered.

FDA's Bernadette M. McMahon, a chemist with the Division of Chemical Technology, reviewed the methodology for PCB detection.

Irving I. Rusoff, Director of Science at the Nabisco Research Center, also reported preliminary findings from PCB studies conducted with the FDA method in 15 industry laboratories to test the method. He said the results showed some "highly significant statistical differences." Rusoff recommended that more work be done, particularly on PCB determinations in untreated paperboard where most of the problems seem to occur. He said the method appeared to be satisfactory for detecting pure PCB.

One of the participants in the GMA-sponsored study cautioned that the work was "preliminary," and it would be a "mistake" to characterize it as a collaborative study in the manner conducted by the Association of Official Analytical Chemists. He said the participants had not yet studied the results, and said any analysis of the results at this time might be putting the "cart before the horse."

William B. Papageorge, Monsanto's Manager of Environmental Protection, described the various types and uses of PCB since the introduction of the compounds in 1929 until the Aug. 30, 1970, announcement that all but closed system uses would be discontinued. He described the important fire resistant characteristics of PCBs that made use essential in heat transformers and capacitors in closed systems, except for plants engaged in packaging, food processing (for humans and animals) and pharmaceutical manufacturing.

On the eve of the meeting, Rep. Gude (R-Md.) asked the Council on Environmental Quality to study the effects of PCBs on Chesapeake Bay fish and shellfish, after discovery of small amounts in softshell clams.

ROGERS PREDICTS NEW FOOD INSPECTION AGENCY IN HEW

Chairman Rogers (D-Fla.) of the House Public Health and Environment subcommittee last week predicted that Congress would vote to realign food inspection services in a new agency in the Department of Health, Education, and Welfare that would combine the meat and poultry operations of the Department of Agriculture with the Food and Drug Administration's food programs.

Citing the General Accounting Office report on poultry operations as additional evidence that something needs to be done (See story, Page 24), Rogers told a PCB Workshop, sponsored by the Grocery Manufacturers of America, he would expect that "you're going to see a combining of food inspection services," and he said it would probably be some sort of a Bureau of Food Inspection apart from FDA, but operating in HEW.

President Nixon's reorganization plan originally called for a disbanding of the Department of Agriculture and envisioned a new agency that would combine FDA with USDA's meat and poultry inspection services in a new HEW agency (See FOOD CHEMICAL NEWS, March 29, Page 32).

In announcing the appointment of Earl L. Butz of Purdue to succeed Clifford Hardin as Agriculture Secretary, President Nixon said he was shelving the plan to disband USDA. (A number of Senators testified against Butz' appointment at nomination hearings last week.)

There has been considerable interest in Congress in combining meat, poultry, egg, and new fish inspection controls in an overall food inspection agency in which FDA would play a prominent role.

A GAO report in 1970 criticized the overlapping inspection programs of FDA, USDA, Army, Public Health Service, and States, and recommended a new look at food inspection (See FOOD CHEMICAL NEWS, July 6, 1970, Page 31).

GAO Investigators Are Looking at FDA Operations

GAO investigators have been camped at FDA for some time, and are believed looking into the inspection operations, among other areas.

In his speech, Rogers said Congress is going to give a new push to the food area, and he noted the criticism of the Nader Report on USDA that pointed to a "conflict of interest" in the Department promoting agriculture that was also responsible for inspection of food establishments.

He also indicated dissatisfaction with FDA, but blamed most of the agency's problems on its lack of manpower and resources. Rogers conducted an investigation of food inspection while looking into the Bon Vivant and Campbell soup problems (See FOOD CHEMICAL NEWS, Sept. 20, Pages 12 and 15).

The chairman of the subcommittee claimed that the Administration hasn't asked for the resources necessary for FDA to do the best job, and, as a result, Congress has not voted the money. He said he was chagrined to learn that FDA gets into some food plants at best once in every four or six years.

On the PCB incident, Rogers said the Government moved a "little slow," and he said concern is growing in Congress and elsewhere on the problem. He commended the industry for taking steps to avoid PCB contamination.

Rogers also had words of praise for the National Canners Association for proposing a new program of controls, noting that it is a "kind of change" for industry to request new rules (See FOOD CHEMICAL NEWS, Nov. 15, Page 41).

"A whole new trend is developing," Rogers told the GMA meeting, which he called a "healthy change." He said he hoped it would continue, and industry would support FDA efforts in order to avoid the "crash programs" that usually spell disaster.

He reminded the industry officials "you can't sweep the problems under the rug for long."

AMI TESTS TO HELP SET NEW NITRITE, NITRATE LEVELS FOR MEAT

Results from the American Meat Institute Foundation's study to evaluate the effect of nitrite and nitrate on toxin production from Clostridium botulinum in perishable canned comminuted cured meat will help the Department of Agriculture set new levels for use as a meat preservative (See FOOD CHEMICAL NEWS, Nov. 1, Page 17).

The study, which is being conducted at the Swift Research Laboratories, Oak Brook, Ill., is being monitored by USDA and the Food and Drug Administration, which has come under criticism for levels it allows for nitrites and nitrates in fish (See FOOD CHEMICAL NEWS, June 14, Page 11).

USDA allows up to 200 p.p.m. of sodium nitrite and up to 500 p.p.m. of sodium nitrate in meat products. Current concern over the substances stems from the possible formation from their use of nitrosamines, which are considered carcinogenic.

In recent testimony, Consumer and Marketing Service Director Clayton Yeutter reported findings by the Agricultural Research Service of nitrosamines in sausages (See FOOD CHEMICAL NEWS, Nov. 15, Page 23), which is believed to be the first time nitrosamines have been detected in meat products. FDA-ers have reported nitrosamine recoveries in fish.

Analyses of samples from two brands of hot dogs showed levels of one up to 80 p.p.b., and lesser amounts in the other. The hot dogs were included in an ARS survey of meat products from the retail level, which were negative for nitrosamines in all other meats.