FOOD CHEMICAL NEWS

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October 4, 1971

FDA OPPOSES PCB BAN, TAKES ISSUE TO THE PRESS

Food and Drugs Commissioner Edwards sought to choke off a growing volume of news stories on polychlorinated biphenyls in a "full disclosure" press conference last week that detailed FDA actions and studies regarding the compounds and revealed new actions by Monsanto Chemical and paper manufacturers.

Monsanto told FDA in a Sept. 8 meeting, it was disclosed, that PCB sales would be limited to "essential closed system uses with no use in food or feed plants." In a Sept. 3 meeting between FDA and the American Paper Institute, FDA was told that National Cash Register had discontinued PCB use in copy paper.

It was also disclosed during questioning that manufacturers' trim from the so-called "carbonless copy paper" that had been routinely used in recycled paper until recently is no longer being used for packaging. Representatives of paper manufacturers said at the press conference that any such copy paper picked up hereafter in recycling programs would not tend to be put into food-grade paper.

It was disclosed outside of the press conference last week that FDA is seeking eight injunctions against shippers and smokers of chubs from the Great Lakes. Of 53 Lake Michigan samples, FDA found 9 with more than 5 p.p.m. PCB and 37 with over 5 p.p.m. DDT.

Both FDA and Agriculture Department officials said that the cause of contamination in 50,000 turkeys in Minnesota has not yet been established (See FOOD CHEMICAL NEWS, Sept. 27, Page 30).

However, Clayton Yeutter, Administrator of USDA's Consumer and Marketing Service, said CMS is reducing its testing in Minnesota and the Dakotas because the contamination was "an isolated occurrence." In a press release, USDA said:

> "All the turkeys were produced, under grower contracts, by a single company and consumed feed produced by the company's mill in Wadena, Minn. The mill's output of feed is used only for the one company's turkeys.
>
> "CMS officials said results of tests by a private laboratory -- and confirmed by CMS laboratories -- on live turkeys at eight farms that contract with the company show that no birds exceed the FDA administrative guidelines.



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> "Samples from turkeys produced by other growers in Minnesota, North Dakota and South Dakota also were within acceptable levels."

FDA's Edwards bluntly resisted a recently renewed call by Rep. Ryan (D-N.Y.) for legislation banning all uses of PCBs. Edwards said:

> "We reject the need and in fact the feasibility as some have proposed for an outright ban on the substances. Although the use of PCBs requires control, an outright ban is not feasible and would not be in the best interest of the consumer."

The reason for the hastily-called press conference was noted in Edwards' reference to "crisis headlines and demands for national health alerts." Washington papers have been running the series of PCB incidents on front and editorial pages, and Ralph Nader's associates have continued to question FDA's handling of the incidents.

In a Sept. 20 letter to Edwards, Nader renewed several earlier charges (See FOOD CHEMICAL NEWS, August 23, Page 20), and Nader said Edwards was posing false issues in referring to "emotionalism, scare headlines, and good science." Nader said:

> "FDA does not serve the cause of rationality and public confidence when it conceals the facts from a public which . . . wants more information about the product he buys and whose questions cannot be ignored.
>
> "The 'good science' that you invoke does not challenge the existence of long-term hazards from persistent low-level accumulations of such substances, nor does science, good or bad, have anything to say about the obligation of FDA to tell the public the <u>full</u> truth in timely fashion. Moreover, your own scientists are far from united concerning the accuracy or responsibility of FDA's public statements during this crisis."

Giving the press conference the air of a "command performance," Edwards was accompanied by Deputy Commissioner James Grant; Reo Duggan, FDA Deputy Associate Commissioner for Compliance; Bureau of Foods Director Virgil Wodicka and Deputy Director Albert Kolbye, Jr. The latter set forth current information on PCB toxicity.

Kolbye prefaced his remarks with the statement, " . . . All available evidence indicates that PCBs (in terms of acute toxicity) are classifiable as being of moderate toxicity." He noted that PCBs are less toxic than DDT, which is one of the safest pesticides in acute toxicity terms. He reviewed toxicity findings from a Japanese incident and rat and mice studies which showed alterations of liver metabolism and other damage. He said:

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> "Animal and human data both point to 150 to 300 micrograms per day as being in the range of safety as far as a temporary dietary intake over the relatively short period of time that we as a society will be forced to tolerate the presence of these chemicals in our food supply.
>
> "Since 2,000 milligrams was reported to be the total dose causing an effect in the Japanese, then 200 milligram total dosage PCBs can probably be tolerated over a protracted period of time without significant adverse effect.
>
> "It would take 22 months of daily ingestion of 300 micrograms of PCBs to arrive at a total ingestion of 200 milligrams . . ."

He also said FDA is not aware of any foods contaminated at significant levels on a regular and consistent basis.

Kolbye spoke the day after the press conference to a Governors' Five-State Interdisciplinary Pesticide Council meeting in Chicago, elaborating toxicity data and stating:

> "To summarize what is presently known, the no-effect level in test mammals may approximate 10 p.p.m. in the diet. Based on this animal data, with allowance for a 1,500 gm human dietary food intake, the Acceptable Daily Intake would permit a 100-fold margin of safety if set at 150 micrograms PCBs per day."

Hinting at the possibility of future guideline action, he said that until long-range feeding studies being conducted by Monsanto have been completed, FDA is unwilling to establish formal guideline levels for PCBs in food.

During the press conference, FDA's Duggan reported on FDA market basket testing for PCBs and testing of packaging materials. Of 720 composite samples during fiscal years 1970 and 1971, 22 were found to contain PCB residues ranging from a trace to 0.36 p.p.m. In three cases, the source of the PCBs were packaging materials. No PCBs have been found in fresh fruits or vegetables, he noted. Tabulations appended to Duggan's statement showed separate breakdowns for packaging and for foods. MONS 031872

The following levels of PCBs were found in various types of packaging:

Gardner board, 73 p.p.m.; Sulfate board, 1.7 to 4.7; Paperboard food packaging, 29 to 433; Chip board, 46; cartons for shredded wheat, 14 to 18; cookie boxes, 33; cracker boxes, 99 to 132; spaghetti and noodle cartons, 12 to 21; powdered sugar, 17; cartons for white hominy grits, 16 to 39; cereals, 29 to 47; and corn meal and mixes, 6.7 to 12.

However, fewer foods were found to be contaminated. The list included:

Shredded wheat in cardboard cartons, none to 0.5 p.p.m.; spaghetti and noodle dinners, 0.3 to 3.0; quick grits, 0.4 to 0.6; cereals, 0.8 to 1.9; shredded wheat, 24; corn meal and mixes trace amounts to 0.2.

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However, the same day as FDA's press conference, Ryan renewed his call for legislation and characterized PCBs as "extremely pervasive, persistent poisons which accumulate in body tissues and, at threshold concentrations at present unknown, constitute a severe threat to health." He charged: "FDA officials have repeatedly attempted to lull the public into a false sense of security."

Calling continued reliance on industry self-control inadequate, Ryan said there are no true closed systems. He demanded:

> "The only thing that will insure that future contamination from PCBs does not occur is to eliminate them totally - - as proposed in my legislation, HR 10085.
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> "What is needed is preventive action by the responsible federal agencies and full and timely disclosure of any and all food adulteration and contamination to the American public."

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ALTERNATIVES TO FAT SOURCE LABELING SUGGESTED

The Frozen Potato Products Institute last week suggested to the Food and Drug Administration five possible alternatives to the agency's proposal for fat and oil source label declarations in descending order of predominance (See FOOD CHEMICAL NEWS, Sept. 27, Page 19).

Most of the comments filed recently with FDA have attacked the source labeling proposal. FPPI also hit use of the label terms "hydrogenated," "partially hydrogenated," and "hardened."

As its first-choice alternative, the Institute suggested that the source labeling should "only be required if a representation is made that the product is for special dietary or nutritional use by man." Its second-choice suggestion was that manufacturers should have the option of listing specific oils and fat if they choose.

As a third alternative, FPPI said a product label could "only be required to say whether or not it contains any animal fat at all." As a fourth choice, the letter said ingredients could be listed "by groupings and not by specific content in a particular package (e.g., 'May contain various blends of one or more of beef, corn, cottonseed, soybean, or palm oil')." The group's fifth choice would entail the required listing of any animal. fats or oils.

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Chicago Shortening asked whether there is "something wrong with the word 'Shortening,'" saying if there is anything injurious about it the public should be educated about it. If not, the firm said, there is no reason to change use of the word "shortening."

Enforcement of source labeling would be "impossible," Chicago Shortening said, adding, "This is like prohibition; it will lead to an undesirable element who realize that it is impossible to definitely establish what is hydrogenated and what is not."

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"To the extent practicable, such research shall utilize data on human exposure which relates to consumption patterns and the accumulative effect on human metabolism."

The staff revision also extends from 90 to 180 days the period in which the Food and Drug Administration is required to propose regulations specifying the dangerous materials and the intensive screening procedures that will be followed to eliminate them from the food supply. The new section carries an appeal procedure for persons adversely affected by these FDA decisions.

New safeguards are also written into the bill to allow firms to seek injunctions against FDA in cases in which the agency attempts to lift a certificate, which is a requirement for operation. A firm may also sue for an injunction of decisions by FDA to withhold approval of labeling or packaging of fish or fishery products, which must be submitted to FDA for pre-clearance under procedures similar to the Department of Agriculture control of meat and poultry labeling and packaging.

In another change, the bill now makes the use of an "official mark" discretionary. Originally, the bill required the mark or the official inspection legend on all fish packages. The National Canners Association, in comments submitted informally on a previous draft, pointed out that the legend or mark is unnecessary because all fishery products become subject to approved inspection programs (See FOOD CHEMICAL NEWS, July 19, Page 30).

In another change, the bill permits fish or fishery products that are in a perishable form to be processed to the extent necessary to prevent spoilage, in cases where FDA segregates products it believes may be adulterated. After segregation for 10 days, the product may be condemned, unless an objection is made. The firm is then provided with a hearing and an opportunity for judicial review.

Under the new Hart bill, "continuous inspection" is defined as inspection "by an inspector at least once daily or at such less frequent intervals as may be prescribed . . . where daily inspection cannot reasonably be provided because of the illness, weather, or other extreme conditions beyond the control of the inspector."

As a part of such inspection, the bill says, an inspector may be required to be "on duty at all times during which the processor is operating or that the processor himself be instructed to monitor the operations or the fish and fishery products of the establishment in the absence of the inspector."

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RECALLS: TROUT, CATFISH CHOWS; FISHMEAL, MEATMEAL

The Ralston Purina Co., St. Louis, Mo., was voluntarily recalling nationwide from users seven varieties of Purina Trout Chow and four varieties of Catfish Chow produced at its Richmond, Ind., and Memphis, Tenn., plants because of contamination with polychlorinated biphenyls.

The Purina Trout Chow had been previously involved in a seizure (See FOOD CHEMICAL NEWS, Sept. 27, Page 24).

Other recalls on the Food and Drug Administration's weekly list involving PCBs included: (1) Fishmeal in bulk being recalled voluntarily from users in the Southeastern States by South Pacific Proteins, Inc., Darien, Conn., from meal processed at the East Coast Terminal, Wilmington, N.C.; and (2) Meatmeal in bulk being recalled voluntarily from a single retailer in Springfield, Ill., by National By-Products, Inc., Mason City, Ill., from meal manufactured by Penn Tallow Co., Pittsburgh, Pa.

The list also included several voluntary recalls by Haver-Lockhart Laboratories, Kansas City, Mo., from wholesalers in the United States and Canada of Neo-plus products, which contain neomycin plus triple sulfas, which had been found "probably not effective" in the review of pre-1962 veterinary products conducted for FDA by the National Academy of Sciences.

An FDA-initiated recall was being carried out in Puerto Rico by Masti-Kure Products Co., Norwich, Conn., of Dr. Garcia Poly Neo Formula mastitis treatment, distributed by Dr. A. Garcia Bird, Div., M. Rio Pedras, Puerto Rico, because the penicillin content was subpotent. FDA said it contained 77.9% of declared potency.

Meanwhile, FDA cleared recently the following New Animal Drugs:

(1) §135b.39 was issued Sept. 21 to clear sodium thiamylal injection as an anesthetic in dogs, on veterinary Rx legend. Sponsor of the new regulation is Phillips Roxane. (2) §135c.41 was issued Sept. 21 to clear sulfamethoxypyridazine tablets and §135c.42 to clear acetyl sulfamethoxypyridazine oral suspension for use in dogs and cats for sulfa-susceptible gram-positive and gram-negative bacterial infections, on veterinary Rx legend. The sponsor is Parke,.Davis. (3) §135c.47 for ampicillin trihydrate capsules, veterinary, was amended Sept. 22 to clear use in cats for treatment of sensitive gram-negative and gram-positive organisms, on veterinary Rx legend. The change was proposed by Squibb.

In other activity, FDA finalized Sept. 30 a list of 703 NADAs of 222 manufacturers proposed for revocation as a result of NAS findings that the products were not effective (See FOOD CHEMICAL NEWS, May 3, Page 19).

GRAS STATUS CLARIFIED BY CYCLAMATE INDEMNITY HEARINGS

Cyclamate indemnity hearings last week before a House Judiciary subcommittee triggered a public review of the uses and possible abuses of the "generally recognized as safe" list.

The day before the hearings, on Sept. 28, FDA spelled out its disclaimer against manufacturer and processor reliance on the GRAS list (See FOOD CHEMICAL NEWS, Sept. 20, Page 7). FDA said in the Federal Register notice:

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