re: O'Neill Collins

POLYCHLORINATED BIPHENYLS

Certain polychlorinated biphenyls are carcinogenic in mice and rats after oral administration, producing liver tumours.[1]

A slight increase in the incidence of cancer, particularly melanoma of the skin, has been reported in a small group of men exposed occupationally to Arochlor 1254, a mixture of polychlorinated biphenyls.[1,2]

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[1]IARC Monographs 18:43-103, 1978.
[2]IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans, Supplement I. IARC, Lyon, France, p. 41, 1979.

Polychlorinated biphenyls (PCBs) vary in appearance from mobile, oily liquids to white crystalline solids to hard noncrystalline resins, with all forms insoluble in water.

Before 1972, PCBs were used in transformer cooling liquids, heat transfer and hydraulic fluids, vacuum pump fluids, lubricants, plasticizers, fillers in investment casting waxes, surface coatings and sealants, pesticide extenders, and for copy paper. By 1974, all domestic uses of PCBs were confined to closed systems.

PCBs have been produced in the United States since 1929. Domestic production reached a peak volume of about 86 million lb in 1970 and decreased to approximately 41 million lb by 1974. Annual domestic production prior to 1977 was approximately 35 million lb. Except for limited research and development applications, the PCBs are no longer produced in the United States, and no import or export of the compounds has been permitted since July 1979.

The release of PCBs from prior industrial uses and the persistence of the compounds in the environment have resulted in widespread contamination of water and soil with subsequent exposure of the general public. Routes of exposure include skin absorption and ingestion; a major source of exposure is through the diet. A 1976 report indicated that fish, cheese, eggs, and contaminated animal feed were the major U.S. commodities in which PCBs were found. Other data showed that the percentage of food samples contaminated with PCBs decreased between 1973 and 1975. Residues of PCBs have been detected in human milk and fat samples collected from the general U.S. population. EPA reports that approximately 12 million persons within 12 miles of three existing and nine projected commercial incinerators could be exposed to releases of PCBs.

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In 1970, EPA banned PCBs as a pesticide ingredient and canceled registration of products containing the PCBs. EPA promulgated toxic pollutant effluent standards in 1977, and the marking and disposal rule in 1978. This latter regulation has been effective in source identification and the elimination of some sources. In 1979, EPA issued a ban on manufacturing, processing, and distribution of PCBs in commerce; most manufacturing had ceased voluntarily before these rules were issued. EPA proposed a water quality criteria document that will protect freshwater, saltwater, and aquatic organisms, as well as human health. Air pollution sources of PCBs were recently assessed by EPA, and the need for regulation of emissions from incinerators, the only source for which controls may be essential, is under consideration. Under the Safe Drinking Water Act, EPA is preparing a report to Congress concerning the nature and extent of PCB contamination, as well as recommendations for further regulatory action if necessary. In 1973, FDA established tolerances for PCBs in several foods and in feeds for food-producing animals. In 1979, four of those tolerances were reduced. The current tolerances are: 1.5 ppm (fat basis) in milk and manufactured dairy products; 3 ppm (fat basis) in poultry; 0.3 ppm in eggs; 0.2 ppm in finished animal feed; 2 ppm in animal feed components of animal origin; 5 ppm in fish and shellfish (edible portion); 0.2 ppm in infant and junior foods. There are also action levels of 3 ppm (fat basis) in red meat and 10 ppm in paper food-packaging material. OSHA has adopted an 8-hour time-weighted average standard of 1 mg/m^3 for PCBs containing 42 percent chlorine, and 0.5 mg/m^3 for PCBs containing 54 percent chlorine. This standard was adopted by OSHA for toxic effects other than cancer.

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REGULATIONS

Regulations and Other Actions	Effect of Regulations and Other Comments	Citation of Regulation
FIFRA, 6: Banned as active or inert ingredient of pesticides (with polychlorinated terphenyls). Registration of products not reformulated, canceled 10/29/70.	Effectively removed pesticides as source of exposure.	PB notice 70-75 sent to all registrants affected.
TSCA, 6: Marking and disposal rule. Promulgated 2/17/78.	Sources have been identified. Wastes are being isolated and/or destroyed. Some sources have been eliminated.	40 CFR 761.18, 761.20
Ban on manufacturing, processing, and distribution in commerce (including some modifications to marking and disposal rule). Promulgated 5/31/79.	Most manufacturing has been voluntarily discontinued prior to these rules (except for certain R&D applications).	40 CFR 761
CWA, 304(a): Water quality criteria document published in final 11/28/80. A concentration of 0.08 ng/l is estimated to limit cancer risk to one in a million.		45 FR 231, p. 79318
CWA, 307(a): Toxic pollutant effluent standard. Promulgated 8/28/79.		40 CFR 129.105
CWA, 311: Hazardous spill regulation, establishing reportable quantity (10 lb, 4.54 kg), and imposing reporting requirements. Promulgated 8/29/79.	Not based on carcinogenicity. Encourages greater care in handling and shipment of chemicals, and should result in reduction of accidental exposures.	40 CFR 117.3,.117.13
RCRA, 3001-3004: Proposed rule included six Aroclor compounds in list of toxic wastes, 12/18/78.	Final rule did not include these, as the TSCA disposal rule addressed PCBs in a more stringent fashion than had been considered.	43 FR 243, p. 58946
Designates PCBs as hazardous constituents of wastes and subjects them to special handling, report/recordkeeping requirements. Promulgated 5/19/80.		40 CFR 261.11
RCRA, 4004: Prohibition on open burning, use on food, croplands, or open dumping of municipal sludges designated hazardous. Promulgated 9/13/79.	Prohibition on food cropland specifically addresses PCBs.	40 CFR 257
CAA: Assessment of sources completed, 5/80. Under review to determine if regulation is warranted. Decision anticipated in first half of FY81.	Incinerators deemed only source that may require control in view of TSCA bans. (EPA)	OAQPS, draft source assessment, 5/80
SNIA: Report to Congress, now in preparation, will document nature and extent of PCB contamination, treatment, and other implications, and establish what, if any, controls may be needed. Schedule for completion, second half of FY81.		OSW, personal communication, 8/80 (EPA)
See Carcinogen Assessment Group statement under 2-acetylaminofluorene. (EPA)		

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rinated Biphenyls (Concluded)

REGULATIONS

Regulations and Other Actions	Effect of Regulations and Other Comments	Citation of Regulation
4, 406: Tolerances for PCBs as unavoidable contaminants in certain foods and al foods established 7/6/73. Four rances reduced 6/29/79.	Holds human exposure to lowest practicable level.	21 CFR 109.30, 509.30
um level of 3 ppm (fat basis) for red t established 6/10/80. (FDA)	Holds human exposure to lowest practicable level. (FDA)	CFR 7111.02 (FDA)
: 1 mg/m³ 8-hr TWA (42 percent orine), 0.5 mg/m³ 8-hr TWA percent chlorine).	Regulatory History: 1952: Walsh-Healy, 1 mg/m³ maximum allowable concentration.	29 CFR 1910.1000 (OSHA)
ential for skin absorption noted. tandard adopted for toxic effects her than cancer.] (OSHA)	8/27/71: OSHA Takeover Standard--current limit effective. (OSHA)	

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