State of California | Department of Health Services

Memorandum

To : Steven A. Book, Ph.D.
Science Advisor to the Secretary
Health and Welfare Agency
1600 Ninth Street, Room 460

Date : August 21, 1989

Subject: Risk Specific Intake Level for PBBs

From : Office of the Director
714 P Street, Room 1253
5-1248

Polybrominated biphenyls (PBBs) were listed on January 1, 1988 as chemicals known to the State to cause cancer under the Safe Drinking Water and Toxic Enforcement Act of 1986 (California Health and Safety Code 25249.5 et seq.). The International Agency for Research on Cancer (IARC, 1987) has classified PBBs as 2B carcinogens ("possibly carcinogenic to humans") and the United States Environmental Protection Agency (U. S. EPA, 1988) has classified PBBs as B2 carcinogens ("probable human carcinogen(s)"). In response to a recommendation by the Scientific Advisory Panel (SAP), the Health and Welfare Agency (HWA) requested that the Department of Health Services (DHS) review and establish a cancer risk assessment for PBBs by July 1, 1989 (HWA, Notice to Interested Parties, Updated and Revised Schedule of Risk Assessments for Proposition 65, January 1, 1989). This memorandum is written in response to that request.

Recommendation

Following the recommendation of the SAP made during the April 14, 1989 meeting, DHS evaluated the need for a cancer risk assessment of PBBs on the basis of the potential for significant exposure to Californians. PBBs are no longer being produced, imported into, or used in the U. S., and current exposure to Californians as a result of past uses or current imports appears to be limited. Therefore, it is unlikely that many Californians might be exposed to significant amounts of PBBs. DHS therefore recommends that a detailed *de novo* risk assessment for PBBs not be performed and that risk estimates be based on default assumptions specified in the regulations adopted by HWA for calculating cancer risk (22 CCR Sections 12701-12721). Following these assumptions, the intake level associated with a 10^{-5} risk of cancer is 0.02 micrograms per day. A summary of available information pertaining to exposure to PBBs and cancer potency estimates follows.

Production

PBBs were used as flame-retardant additives in synthetic fibers and molded thermoplastic parts (EPA, 1979). They were manufactured in the U. S. only during the 1970s. Laboratory quantities of no more than 2 kilograms per year (kg/yr) may have been produced in California.

PBBs were produced in commercial quantities in the U. S. at two facilities: the Michigan Chemical Company (MCC) produced "Firemaster BP-6", a mixture of PBBs containing primarily hexabrominated biphenyls at its facility in St. Louis, Michigan; White Chemical Corporation produced octa- and deca-bromobiphenyls at its plant in Bayonne, New Jersey (EPA, 1975; EPA, 1979). Nine domestic chemical suppliers produced or imported small quantities of less than 2 kg/yr. One of these small volume suppliers, Biochemical Laboratories, Inc., was located in Hawthorne, California.

The most significant exposures of the general public to PBBs occurred in Michigan in 1973 when the flame retardant Firemaster BP-6 was accidentally mixed into cattle feed which was subsequently used on over 500 Michigan farms (Humphrey, 1989; Fries, 1986; EPA, 1975). Commercial production of hexabromobiphenyl in the U. S. was halted in November 1974, following this incident (IARC, 1986). The sole U. S. producer of hexabromobiphenyl, MCC, had depleted its remaining stock by April 1975 (IARC, 1986). MCC's plant was closed and has been designated as a hazardous site by the Michigan Department of Health (Humphrey, personal communication). White Chemical Corporation ceased production in 1979. The only supplier of PBBs in 1978, Fine Organics, Inc., sold only small quantities of less than 2 kg/yr (EPA, 1975, 1979).

One company in France currently produces commercial quantities of decabromobiphenyl (IARC, 1986). Under the Toxic Substances Control Act, manufacturers and importers of PBBs are required to notify EPA (1984). During the period of greatest PBB use, EPA (1979) found no indications that significant quantities of PBBs were being imported into the U. S. DiCarlo *et al.* (1978) reported that PBBs were being exported in the 1970s, and estimates 805,000 pounds were exported from the U. S. in 1976. Dr. T. Mohin of EPA indicated that under SARA Title 313, EPA requires reporting of any use in the U. S. of PBBs, including importation; no such use has been reported to date. DHS found a notice on the importation of PBBs into the U. S. reported in the Federal Register in 1980 prior to the reporting requirement under SARA (EPA, 1980).

<u>Use</u>

The EPA (1979) has summarized commercial uses of PBBs as follows:

> "Used by manufacturers in the plastic, resin, and synthetic fiber industry, they are added to polymers (thermoplastic resins) in mixing and blending steps after polymerization. PBBs may be added to fiber polymers during spinning and finishing operations. PBBs have been incorporated into the plastic housings of many commercial products, such as typewriters, calculators, and microfilm readers; and consumer products, such as radio and television parts, thermostats, shavers and hand tools."

> "Octabromobiphenyls, produced by Great Lakes Chemical Corp. [*Michigan Chemical Co.*], was used as a flame retardant in acrylonitrile-butadiene-styrene (ABS) and polyolefin resins. PBBs manufactured by White Chemical Corp. were sold to manufacturers of polycarbonates, polyesters, polyolefins, and polystyrene."

DiCarlo *et al.* (1978) reported that more than 60% of the total production of PBBs was used to fireproof carpets and rugs, with the remaining 40% impregnated into clothing, home furnishings and construction, electrical and electronic products. Earlier uses were limited applications in thermoplastic production. In 1974, approximately 55% of Firemaster BP-6 made was added to ABS-based resins produced by the Borg-Warner Corporation. One of the three facilities producing these resins was located in Oxnard, California. No information was available in EPA (1975, 1979) reports on possible contamination resulting from this and other fire retardant resin and fabric manufacture.

Environmental Occurrence and Exposure

Environmental contamination by PBBs is primarily limited to areas near the commercial production facilities and those contaminated in the Firemaster incident of Michigan (Fries, 1986; DeCarlo, 1979; EPA, 1975; EPA, 1979). PBBs do not readily leach from the thermoplastic products into which they have been incorporated. Information is not available on the extent of migration of PBBs from treated fabric. The useful life of most PBB containing products has been estimated to be approximately 5-10 years at which time they are typically discarded or buried in a sanitary landfill (DiCarlo et al., 1978). EPA (1979) notes the possibility of environmental contamination as a result of fires in dumpsites where products containing PBBs have been discarded. In such situations PBB-laden ash might be generated.

Although PBBs are persistent in soils, plants grown on PBB-contaminated sites in Michigan did not have elevated PBB levels (Jacobs *et al.*, 1976). PBBs are bound tightly by clay minerals and various soils, and may remain in the soil for years, and may possibly be ingested by farm animals (DiCarlo *et al.*, 1978). The accidental contamination of animal feed in Michigan following the Firemaster incident resulted in PBBs in meat and dairy products which were subsequently consumed by humans (Fries, 1986; EPA, 1975; Landrigan *et al.*, 1979). Human exposure to PBBs resulting from this incident occurred primarily in Michigan; low levels were also detected in farm products from neighboring states (DiCarlo *et al.*, 1978).

Detection of PBBs in California

PBBs are not perceived to be an environmental problem for drinking water or outdoor air in California. Dr. David Spath of the DHS Public Water Supply Branch indicated that the State does not monitor for the presence of PBBs in

Californians' drinking water. Dr. Spath noted that due to their extremely low water solubility PBBs are unlikely to migrate far via water from the site of a spill. Dr. Spath has noted that polychlorinated biphenyls, which have physical properties very similar to these of PBBs, do not migrate far from spill sites in water. Dr. M. Redgrave of the California Air Resources Board (ARB) indicated that ARB does not routinely monitor for PBBs in California air because their occurrence is so unlikely. Dr. Jerry Pollock of DHS Hazard Evaluation Section indicated for the same reasons that fish are not analyzed for PBB contamination. Mr. Goodspeed of the U. S. Department of Agriculture Western Laboratories indicated that PBBs have never been detected in California's meat supply, despite routine monitoring.

Cancer Potency and No Significant Risk Intake Level Estimate

PBBs have been observed to produce liver tumors in a number of studies in rats and mice. The bioassays in rat and mice studies performed by the National Toxicology Program and reported by Gupta *et al.* (1983) are the most pertinent studies for the calculation of cancer potencies: multiple dose levels were used; dosing was chronic; and the observation periods were sufficiently long. Groups of Fischer 344 rats and $B6C3F_1$ mice were given PBBs 5 times per week over a 6 month period at 0, 0.1, 0.3, 1.0, 3.0 and 10.0 mg/kg/day and observed for an additional 23 months for rats and 24 months for mice. Significantly higher incidences of atypical hepatocellular foci, neoplastic nodules, hepatocellular carcinomas, and cholangiocarcinomas were observed in exposed rats and hepatocellular carcinomas were observed in male and female mice. Following "Guidelines for Chemical Carcinogen Risk Assessment and Their Scientific Rationale" (DHS, 1985) and Title 22 Section 12703 of the California Code of Regulations, cancer potency is estimated from the most sensitive study of sufficient quality; the upper 95% confidence bound on the linear term of the multistage model is taken as the estimate of potency, after correcting for differences in size between test animals and humans. DHS performed this analysis and determined that the most sensitive study of sufficient quality was that reported by Gupta *et al.* (1983) for male $B6C3F_1$ mice. From the dose response data for hepatocellular carcinoma observed in these male mice a potency estimate of 30 $(mg/kg\text{-}day)^{-1}$ was derived. This corresponds to an intake of 0.02 micrograms per day for an increased risk of 10^{-5}.

Summary

Significant environmental exposures to PBBs involving large numbers of Californians are unlikely to occur. Evidence indicates that PBBs are not currently being produced or used in the U. S. Only small amounts of PBBs have ever been produced in California. With regard to exposure resulting from past practices, PBBs do not leach from thermoplastics, the major product containing PBBs. There is the small chance of PBB exposure to neighboring communities and workers at disposal sites where products

containing PBBs have been discarded. The extent to which this may be a problem requires further investigation. Nonetheless, the overall chance of significant exposure of Californians to PBBs appears to be very small. Therefore, DHS recommends that the resources necessary for a detailed *de novo* cancer risk assessment of PBBs be spent on assessment of other carcinogens to which Californians are more likely to be exposed and that the risk assessment for PBBs be based on default assumptions. An intake level of 0.02 micrograms per day is therefore found to represent a 10^{-5} risk of cancer, the no significant risk level established by HWA for the purposes of Proposition 65.

Please contact Richard J. Jackson, M.D., M.P.H., Chief, Office of Environmental Health Hazard Assessment at 4-7572 ,if you have any questions about the derivation of the risk specific intake level for PBBs.

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Director

REFERENCES

California Department of Health Services (1985). *Guidelines for Chemical Carcinogen Risk Assessment and Their Scientific Rational.* California Department of Health Services, Health and Welfare Agency, Sacramento, CA.

DeCarlo VJ (1979). Studies on brominated chemicals in the environment. *Annals of the New York Academy of Sciences* 320:678.

DiCarlo FJ, Seifter J, DeCarli VH (1978). *Assessment of the Hazards of Polybrominated biphenyls.* USEPA-560/6-77-037. EPA Office of Toxic Substances, Washington, D.C., April.

Environmental Protection Agency (EPA, 1975). *Survey of Industrial Processing Data. Task II - Pollution Potential of Polybrominated Biphenyls.* EPA-560-3-75-004. EPA Office of Toxic Substances, Washington, D.C.

Environmental Protection Agency (EPA, 1979). *Status Assessment of Toxic Chemicals: Polybrominated Biphenyls.* USEPA 600/2-79-210K EPA Office of Research and Development, Industrial Environmental Research Laboratory, Cincinnati, OH.

Environmental Protection Agency (EPA, 1980). Submission of notices of manufacture or import of PBBs and Tris. Federal Register 45 70728.

Environmental Protection Agency (EPA, 1984). Polybrominated biphenyls (PBBs). *U. S. Code Federal Regulations*, Title 40, Part 704.195, pp 579-581.

Fries GF (1986). The PBB Episode in Michigan: An overall appraisal. *CRC Critical Reviews in Toxicology* 16(2):105-106.

Goodspeed DP. Supervisory Chemist, Director of Chemical Analysis, USDA Western Laboratories, Alameda, California. Private communication.

Gupta BN, McConnell EE, Moore JA, Haseman JK (1983). Effects of a polybrominated biphenyl mixture in the rat and mouse. II. Lifetime Study. *Tox Appl Pharmacol* 68:19-35.

Humphrey H (1974). Environmental Epidemiologist, Director of epidemiologic follow-up on Firemaster incident, Bureau of Community Health, Michigan Department of Health, personal communication.

Humphrey HEB (1989). Exposure to environmental contaminants: Human health effects assessment. *Balancing the scales: Weighing the benefits and risks of fish consumption*, Proceedings of a workshop held by California Department of Health Services, October 20, 1988.

International Agency for Research on Cancer (1986). *IARC Monographs on the Evaluation of the Carcinogenic Risk of Chemicals to Humans*. 41:261-292.

Jacobs LW, Chou S and Tiedje JM (1976). Fate of polybrominated biphenyls in soils. Persistence and plant update. *Journal of Agricultural and Food Chemistry* 24:1198.

Landrigan PJ, Wilcox KR, Silva J Jr, Humphrey HEB, Kauffman C, Heath CW Jr (1979). Cohort study of Michigan residents exposed to polybrominated biphenyls: epidemiologic and immunologic findings. *Annals New York Academy of Sciences* 320:284.