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Environmental Protection Agency
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COMMENTS ON EPA'S NATIONAL PRIMARY DRINKING WATER REGULATION FOR PCBS

Submitted by the
Polychlorinated Biphenyls Program Panel
of the Chemical Manufacturers Associations

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CHEMICAL MANUFACTURERS ASSOCIATION
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INTRODUCTION

The Chemical Manufacturers Association (CMA) PCB Program Panel welcomes this opportunity to comment on EPA's proposed National Primary Drinking Water Regulations. 50 Fed. Reg. 46936 (Nov. 13, 1985). CMA's PCB Panel has been an active participant in numerous EPA rulemakings, particularly pursuant to the Toxic Substances Control Act (TSCA), concerning PCBs. Throughout its history, the Panel has worked closely with EPA to assure that any PCB regulations are both protective of public health and consistent with reasonable assessment of potential risks.

As detailed in these comments, we urge that EPA revise its proposal establishing a Recommended Maximum Contaminant Level (RMCL) of zero for PCBs in drinking water. EPA errs in its conclusion that PCBs are a Category I probable human carcinogen. To the contrary, there is only limited, inconclusive evidence of animal carcinogenicity. ~~Accordingly, an~~ The proposed RMCL for PCBs of zero is unjustified. ~~We propose that~~ The Agency should ~~instead,~~ rely on significant work of the Food and Drug Administration (FDA) to assess potential risks of PCB in the diet and, following its lead, adopt an RMCL of at least 6.5 micrograms (µg) per liter.

I. THE ONLY EVIDENCE THAT PCBS ARE CARCINOGENIC IS FROM ANIMAL STUDIES THAT ARE LIMITED AND INCONCLUSIVE.

Extensive data exists on PCBs. Highly exposed worker populations have been studied, and the ~~compound~~ chemical has been administered in a wide variety of toxicology studies. Based upon this extensive data base, ~~it is possible to~~ The Agency can reach reasonable conclusions about any potential risk that might be posed from the presence of PCBs in drinking water. Although it is not possible to conclude that absolutely no adverse health effects would be expected, more than enough data exists to indicate that EPA would err by concluding that it should establish a PCB RMCL of zero.

9/ A detailed rebuttal of EPA's PCB Health Advisory was provided the Agency Dec 16, 1985 by Monsanto Co and provides the basis for the conclusion that there is inadequate evidence to base the RMCL for PCBs upon chronic health effects including carcinogenicity. Those comments are incorporated herein by reference and are attached in Appendix I.

considered appropriate. Yusho Oil is not representative PCB heat transfer fluids, as it contained, in addition to PCBs, high levels of polychlorinated dibenzofurans and polychlorinated quarterphenyls. In consideration of these facts, several scientists have concluded that PCBs were not the cause of poisoning in Japan or Taiwan. See Kuratsune, "Yusho," in Halogenated Biphenyls, Triphenyls, Napthalenes, Dibenzodioxins and Related Products (1980); Chen, et al.,

(Footnote Continued)

I. THE ONLY EVIDENCE THAT PCBS ARE CARCINOGENIC IS FROM ANIMAL STUDIES THAT ARE LIMITED AND INCONCLUSIVE.

Extensive data exists on PCBs. Highly exposed worker

A. Epidemiologic Studies of Highly Exposed Worker Populations Have Found No Significant Cancer Increases.

Several epidemiology studies of highly exposed worker populations have found no significant cancer increases. 1/ Studies by Brown and Jones and by Bertazzi, et al., of 2,567

1/ Earlier reliance on studies in Yusho is no longer considered appropriate. Yusho Oil is not representative of PCB heat transfer fluids, as it contained, in addition to PCBs, high levels of polychlorinated dibenzofurans and polychlorinated quarterphenyls. In consideration of these facts, several scientists have concluded that PCBs were not the cause of poisoning in Japan or Taiwan. See Kuratsune, "Yusho," in Halogenated Biphenyls, Triphenyls, Napthalenes, Dibenzodioxins and Related Products (1980); Chen, et al.,

(Footnote Continued)

and 1,310 workers, respectively, exposed for up to more than 20 years, have not demonstrated any ~~consistent~~ statistically significant relationship between exposure to PCBs and the development of any particular cancer. 2/ In addition, the more recent epidemiological review by Lawton, et al., 3/ of medical records of General Electric workers with PCB exposure in electrical capacitor manufacture found only minor dermatological effects, unremarkable physical examinations, and no signs of chloracne past or present. The study demonstrates that extensive exposure to PCBs in the occupational setting, sufficient to have established blood levels in excess of 200 ppb, has not led to any clinical disease states.

(Footnote Continued)

"Polychlorinated Biphenyls, Dibenzofurans, and Quarterphenyls in the Toxic Rice-Bran Oil and PCBs in the Blood of Patients with PCB Poisoning in Japan," 5 Amer. J. Ind. Med. 133 (1984); Kashimoto, et al., "Role of Polychlorianted Dibenzofuran in Yusho (PCB Poisoning)," 36 Arch. Environ. Health 321 (1981); Masuda and Yoshimura, "Polychlorianted Biphenyls and Dibenzofurans in Patients with Yusho and Their Toxicological Significance," 5 Amer. J. Ind. Med. 31 (1984); and Kunita, et al., "Causal Agents of Yusho," 5 Amer. J. Ind. Med. 45 (1984).

2/ Brown, D. P., and M. Jones, "Mortality and Industrial Hygiene Study of Workers Exposed to Polychlorinated Biphenyls," 36 Arch. Environ. Health 120-29 (1981); Bertazzi, P. A., et al., "Mortality Study of Male and Female Workers exposed to PCBs," Paper presented at the International Symposium on Prevention of Occupational Cancer (April 21-24, 1981, Helsinki, Finland).

3/ Lawton, R. W., et al., "Studies of Employees Occupationally Exposed to PCBs," General Electric Progress Report (1981).

The reference in EPA's Health Advisory draft on PCBs (at page 4) to an increase in incidence of malignant melanoma in petrochemical workers exposed to PCBs and other identified chemicals should be afforded no weight. This study 4/ is not adequate to reach conclusions of an association with carcinogenicity due to the small number of individuals exposed and the confounding variable of exposure in the workplace to many other chemicals. Indeed, the study was subsequently withdrawn for revision and has not been reissued. 5/

In sum, substantial human data indicate even heavily exposed workers have not developed serious clinical diseases attributable to PCBs. No significant human evidence of PCB association with any cancer exists.

B. Contrary to EPA's Discussion, All PCBs Have Been Found to Be Non-Mutagenic.

There is also no significant evidence that PCBs are mutagenic in test systems or in human populations. It is thus quite unlikely that PCBs would exert mutagenic activity

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4/ Bahn, A. K., et al., "PCBs and Melanoma," 296 New England J. Med. 108 (1977); Bahn, A. K., et al., "Melanoma After Exposure to PCBs," 295 New England J. Med. 450 (1976).

5/ See NIOSH 1977 Criteria for a Recommended Standard: Occupational Exposure to Polychlorinated Biphenyls (PCBs), USDHEW, NIOSH Publication No. 77-225.

in humans. This conclusion is consistent with the lack of excess cancer incidence observed in PCB-exposed human populations.

EPA's reference to a mutagenicity assay of 4-chlorobiphenyl as being positive, 50 Fed. Reg. at 47002, is inaccurate. That study is contradicted by numerous other mutagenicity assays of ~~PCBs~~ PCBs. 6/ More significantly, the co-author of that study has, since its initial release,

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6/ McMahon, et al., "Assay 855 Test Chemicals in Ten Tester Strains Using a New Modification of the Ames Test for Bacterial Mutagens," 39 Cancer Res. 682 (1979); Environmental Protection Agency, "Ambient Water Quality Criteria for Polychlorinated Biphenyls," EPA 440/5-80-068 PB 81-117798 (1980); Bruce and Heddle, "The Mutagenic Activity of 61 Agents as Determined by the Micronucleus, Salmonella and Sperm Abnormality Assays," 21 Can. J. Genet. Cytol. 319 (1979); Schoeny, et al., "Non-mutagenicity for Salmonella of the Chlorinated Hydrocarbons Aroclor 1254, 1,2,4-trichlorobenzene, mirex and kepone," 68 Mutat. Res. 125 (1979); and, Rinkus and Legator, "Chemical Characterization of 465 Known or Suspected Carcinogens and Their correlation with Mutagenic Activity in the Salmonella Typhimurium System," 39 Cancer Res. 3289 (1979).

Other studies that support the lack of mutagenic activity for PCBs include an absence of effects in the micronucleus test and sperm morphology tests. (Bruce and Heddle (1979) previously cited; Jensen and Ramel, "The Micronucleus Test as Part of a Short-Term Mutagenicity Test Program for the Prediction of Carcinogenicity Evaluated by 143 Agents Tested," 75 Mutat. Res. 191 (1980).

Others have shown that PCBs did not produce chromosomal damage in the testes and bone marrow of rats (Dikshith, et al., "Effect of Polychlorinated Biphenyl (Aroclor 1254) on Rat Testes," 22 Exp. Mol. Path. 376 (1975); and, Garthoff, et al., "Biochemical and Cytogenetic Effects in Rats Caused by Short-Term Ingestion of Aroclor 1254 or Firemaster BP6," 3 Toxicol. Environ. Health 769 (1977).

indicated that he had been unable to replicate the result and that it was his belief that PCBs should not be considered mutagenic. 7/

In sum, no prediction of PCB carcinogenicity can be based on any mutagenicity results.

C. The Inconsistent Bioassay Results Show No More Than Limited, Inconclusive Evidence of Animal Carcinogenicity.

EPA's placement of PCBs in Category I based upon strength of evidence of carcinogenicity is inappropriate. The existing data do not provide "sufficient human or animal evidence of carcinogenicity" to warrant the regulation of PCBs "as probably human carcinogens." 50 Fed. Reg. at 46948. To the contrary, the only possible evidence indicating carcinogenic risk is in the animal data and that data should place PCBs in Category III as it is "inadequate" evidence of carcinogenicity. Id. At a minimum, PCBs should be placed in Category II given that the evidence is "limited inconclusive evidence ... from animal data." Id. This point is addressed in detail in CMA's generic comments on this proposed rule filed separately and is incorporated herein by reference

A sizeable volume of animal experimental work has been directed toward chronic studies of PCBs in several species: the mouse, the rat, and the dog. The data shows: (a) the

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7/ See Affidavit of Dr. Steven Safe submitted to EPA in 1980 by the Dow Chemical Company. A copy of that affidavit is attached as Appendix A to these comments.

evidence on carcinogenicity is negative for gastrointestinal carcinoma and bladder carcinoma in rats and hepatocellular carcinoma in the dog; and (b) some studies have reported an increase in hepatocellular carcinoma in mice and rats exposed to commercial PCBs, whereas other studies have afforded negative results. 8/

Animal studies thus do not provide convincing evidence that PCBs induce liver cancer. Of the major studies in the rat, one has been judged positive and two have been negative. Hepatic carcinoma was not produced in the dog. Chronic administration of Aroclors in the rat did not induce bladder cancer, gastrointestinal carcinomas, or cancer of

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8/ See, Ito, N., et al., "Histopathologic Studies on Liver Tumorigenesis Induced in Mice by Technical Polychlorinated Biphenyls and Its Promoting Effect on Liver Tumors Induced by Benzene Hexachloride," 51 J. Natl. Cancer Inst. 1637 (1973); Kimbrough, R. D. and R. E. Linder, "Induction of Adenofibrosis and Hepatomas of the Liver in BALB/cJ Mice by Polychlorinated Biphenyls (Aroclor 1254)," 53(2) J. Natl. Cancer Inst. 547-52 (1974); Kimbrough, R. D., et al., "Induction of Liver Tumors in Sherman Strain Female Rats by Polychlorinated Biphenyl (Aroclor 1260)," 55 J. Natl. Cancer Inst. 1453-59 (1975); Calandra, J. C., "Summary of Toxicological Studies on Commercial PCBs," Proc. of the National Conference on Polychlorinated Biphenyls Chicago, Ill. (Nov. 19-21, 1975); Calandra, J. C., "Summary of Toxicological Studies on Commercial PCBs," Proc. of the National Conference on Polychlorinated Biphenyls 35-42 (EPA-560/6-75-004) (1976); National Cancer Institute, Bioassay of Aroclor 1254 for Possible Carcinogenicity, No. 38, NEW (1978); Preston, B. D., et al., "Promoting Effects of Polychlorinated Biphenyls (Aroclor 1254) and Polychlorinated Dibenzofuran-free Aroclor 1254 on Diethyl-Nitrosamine-Induced Tumorigenesis in the Rat," 66(3) J. Natl. Cancer Inst. 509-25 (1981).

the thyroid gland, pituitary gland, adrenal gland, uterus, lung, hematopoietic system, or other organs.

Much of the controversy surrounding this issue involves interpretation of the significance of hepatocellular proliferative lesions noted in some but not all chronic studies. The liver is a target organ for PCBs. Chronic administration of sufficiently high levels of PCBs can induce liver injury in animals leading to a proliferative response in hepatic tissue. This response may be reparative in nature and not due to genotoxic interactions, since the majority of short-term assays demonstrate that PCBs are not mutagenic. Based on these considerations, exposure to moderate environmental levels of PCBs would not pose a significant carcinogenic risk to man.

In sum, EPA errs by concluding that PCBs are a probable human carcinogen. There is "inadequate" evidence of carcinogenicity to reach such a conclusion. At best, PCBs should be placed in SDWA Category II given the "limited inconclusive evidence ... from animal data." Accordingly, ~~consistent with RMCLs proposed for other substances at this time, a numerical number other than zero should be established as the RMCL for~~ PCBs.

the PCB RMCL should be set at a level consistent with findings based upon a scientific review of known health effects as discussed in the following section, not zero.

Sufficient data exists to establish a non-zero theoretical RMCL for PCBs.

II. UNJUSTIFIED EXPENDITURE OF SOCIETAL RESOURCES WOULD BE MANDATED BY ESTABLISHMENT OF A ZERO RMCL FOR PCBs.

Should EPA adopt an RMCL of zero for PCBs, it will be required to fashion a Maximum Contaminant Level (MCL) for PCBs that will, in turn, require either monitoring and/or treatment of all drinking water in this country for this substance. As PCBs can be expected to be found in most drinking water supplies only at very low levels, it would be inappropriate to initiate this regulatory action based on an RMCL of zero that will require inevitably much monitoring throughout the country. Much more appropriate, given the limited inconclusive evidence of carcinogenicity, would be determination at this time of a reasonable limit for a PCB RMCL.

Review or delete

~~CMA thus urges that the RMCL for PCBs not be zero.~~ To the extent the Agency feels a need to establish any RMCL, an appropriate basis for such a value would be in FDA's conclusion that the tolerance for PCBs in the diet should be 13 micrograms per day. The Food and Drug Administration has set a tolerance limit of 2 ppm PCBs in fish (21 C.F.R. Part 109). Assuming an average person's daily consumption of PCBs in fish is 6.5 µg/day, the average daily consumption of PCBs

would be 13 µg/day. Accordingly, given average human consumption of 2 liters of water per day, the RMCL would be 6.5 µg/liter.

CONCLUSION.

Remove

CMA urges that an RMCL for PCBs be established at a level of at least 6.5 µg/liter. Such an RMCL would be more than adequately protective of the nation's drinking water supplies and would more accurately reflect the substantial epidemiologic and toxicologic information on this substance.