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EPA Region 2

PCBs &Human Health - Q & A

What are PCBs and why is EPA concerned about them?

PCBs or polychlorinated biphenyls are a group of chemicals consisting of 209 individual compounds. PCBs were widely used as a fire preventive and insulator in the manufacture of transformers and capacitors because of their ability to withstand exceptionally high temperatures.

PCBs were banned by the EPA in 1979, and are classified as a probable human carcinogen by numerous national and international health-protective agencies and organizations. Scientific research also links PCB exposure to non-cancer impacts such as developmental and neurological disorders.

PCBs build up (bioaccumulate) in the environment, increasing in concentration with movement up the food chain into larger animals. This is of special concern in areas where fish are exposed to PCBs and may be eaten by humans, thereby increasing the risk of PCB contamination in the human population.

What do other agencies say about cancer and PCBs?

EPA is not alone in its concerns about the carcinogenicity of PCBs (the ability of PCBs to cause cancer). The **International Agency for Research on Cancer (IARC)**, which was established by the **World Health Organization** has declared PCBs a probable human carcinogen based on sufficient evidence in animals and limited evidence in humans. In addition, the **National Toxicology Program**, a part of the **National Institutes of Environment Health Science (NIEHS)**, has concluded that PCBs are reasonably anticipated to be carcinogenic in humans. The **National Institute for Occupational Safety and Health (NIOSH)**, has determined that PCBs are a potential occupational carcinogen.

How is the toxicity of PCBs determined?

To evaluate the potential toxicity of chemicals and the levels associated with the toxicity, EPA uses data from human epidemiological studies (epidemiology is the study of the causes of disease), laboratory animal toxicity studies and supporting information that may also include tests on cells.

Animal toxicity studies are primarily conducted on mice, rats, and to a lesser extent in monkeys. These species share a similar evolutionary history to humans. The studies are conducted with appropriate safeguards including prior approval by institutional review boards on animal experimentation.

Do PCBs cause cancer?

EPA evaluates the ability of a chemical to cause cancer based on the weight of evidence of human epidemiological and animal toxicity studies. EPA also develops risk factors that indicate the relative potency of the chemical (the ability of a given quantity or dose to cause cancer).

Weight of Evidence: PCBs are classified as likely to be carcinogenic in humans. The basis for this determination is a 1996 rat study, sponsored by General Electric; and reviewed by EPA and external peer reviewers. This study found increased numbers of liver tumors in female rats exposed to a number of different PCB compounds, and in male rats exposed to a particular compound (known commercially as Aroclor 1260). The findings of the 1996 GE study strengthened earlier studies which also demonstrated carcinogenicity in rats.

Risk Factors: To quantify the potential for PCBs to cause cancer, EPA developed three cancer slope factors based on the GE rat study. The different cancer slope factors deal with different routes of exposure, and the estimate of excess cancer lifetime risks per dose or exposure to a cancer-causing agent. The highest cancer slope factor is through ingestion (generally in the form of eating contaminated fish).

What about the latest GE study on plant workers that says PCBs are not a cancer risk?

Senior scientists at EPA have reviewed the study of *Kimbrough and Colleagues* in the March 1999 *Journal of Occupational and Environmental Medicine*, titled "Mortality in Male and Female Capacitor Workers Exposed to Polychlorinated Biphenyls." The study reports on the cause of death among workers at two General Electric (GE) plants in upstate New York, and was funded by the General Electric Company.

After reviewing the GE study, EPA does not change its conclusion that the scientific evidence shows that PCBs are probably carcinogenic in humans.

It is important not to read more into the conclusions of the recent study of GE workers than this study can support. The GE study did not review any of the health endpoints of greatest concern for PCBs other than cancer. The study considered only cancer deaths and did not evaluate the risk of getting cancer. In addition, most of the workers in the study were largely unexposed to PCBs.

Moreover, the study was not designed to evaluate risks in the most vulnerable populations exposed to environmental PCBs, including children, the elderly, and those with other health problems. The types of PCBs evaluated in this study were also not the most toxic types of PCBs that tend to accumulate in fish and persist in the environment.

There are other limitations in the study design that raise questions about the conclusions that can be drawn from this study. **Most of the workers in the study (more than 75%) never worked with PCBs, and the actual level of PCB exposure**

in the remaining workers could not be confirmed. In addition, the small percentage of workers who did work with PCBs (less than 25%) were employed in these jobs for less than one year.

Finally, the results of other studies must be considered as well, including recent work sponsored by GE that demonstrated that all four of the PCB mixtures tested were carcinogenic in rats. Likewise, two recent studies associated non-Hodgkins lymphoma in humans with serum and fat PCB levels.

What about other PCB health effects that are not related to cancer, like endocrine disruption?

EPA evaluates all of the available data in determining potential non-cancer toxicity of environmental contaminants, including PCBs. Extensive studies have been conducted in animals, including primates such as rhesus monkeys, using environmentally relevant doses. EPA has found clear evidence that PCBs have significant toxic effects in animals, including effects on the immune system, the reproductive system, the nervous system and the endocrine system. The body's regulation of these systems is complex and interrelated. As a result, it is not surprising that PCBs can exert a multitude of serious adverse health effects, such as:

Immune Effects: The immune system is critical for fighting infections, and diseases of the immune system have very serious potential implications for the health of humans and animals. The immune effects of PCB exposure have been studied in Rhesus monkeys as well as other animals. Please note that the immune systems of Rhesus monkeys and humans are very similar. Studies have shown that PCB exposure has resulted in a significant decrease in the size of the thymus gland (which is critical to immune system function) in infant monkeys, reductions in response of the immune system and decreased resistance to the Epstein-Barr virus and other infections.

Reproductive Effects: Potentially serious reproductive effects have been seen in monkeys exposed to PCB mixtures, including reduced birth weight, conception rates and live birth rates. Studies of reproductive effects have also been carried out in human populations exposed to PCBs. Children born to women who worked with PCBs in factories showed decreased birth weight and a significant decrease in gestational age with increasing exposures to PCBs.

Neurological Effects: Newborn monkeys exposed to PCBs showed persistent and significant deficits in neurological development, including visual recognition, short-term memory and learning. Some of these studies were conducted using the types of PCBs most commonly found in human breast milk. Studies in humans have suggested effects similar to those observed in monkeys exposed to PCBs. The similarity in effects observed in humans and animals provide additional support for the potential neurobehavioral effects of PCBs.

Endocrine Effects: While the significance of endocrine disruption as a widespread

issue in humans and animals is a subject of ongoing study, PCBs have been demonstrated to exert effects on thyroid hormone levels in animals and humans. Thyroid hormone levels are critical for normal growth and development, and alterations in thyroid levels may have significant implications.

What is risk assessment?

Risk assessment is a process used by EPA to determine the potential health effects in humans associated with exposure to chemicals. Risk assessment is used throughout EPA to evaluate chemical toxicity and potential health effects in humans.

Under Superfund Law, EPA is required to conduct a baseline risk assessment that evaluates current and future risks at all Superfund sites. As defined by the National Academy of Sciences in 1983, Risk Assessment involves one or more of the following steps:

1). **Hazard Identification**- Do PCBs have the potential to cause cancer? What other health effects are caused by PCBs?

2). **Dose Response** - What amount of PCBs in the human body causes these effects?

3). **Exposure Assessment** - How people are exposed to PCBs (i.e., eating, drinking, breathing, skin contact) and at what levels.

4). **Risk Characterization** - The answers to the above three questions are used to calculate what risk an individual having significant exposure runs of developing cancer or experiencing a non-cancer effect.

How are risks calculated?

Cancer risk calculates the increased probability of an individual developing cancer based on a number of assumptions concerning PCB exposure. The risks are calculated by multiplying the dose (from exposure) by the toxicity (cancer slope factor). The individual risks for each pathway are added together to reflect the total cancer risk.