COMMONWEALTH of VIRGINIA

Department of Health

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VIRGINIA DEPARTMENT OF HEALTH GUIDELINES FOR ISSUANCE OF FISH CONSUMPTION ADVISORIES DUE TO CONTAMINATION OF FISH WITH POLYCHLORINATED BIPHENYLS (PCBs) (REVISED 2004)

In October 2000, pursuant to § 32.1-248.01, *Code of Virginia*, the Virginia Department of Health (VDH) submitted its guidelines for issuance of fish consumption advisories due to contamination of fish with PCBs to the Chairmen of the House Committee on Health, Welfare and Institutions, the House Committee on Conservation and Natural Resources, the Senate Committee on Education and Health, and the Senate Committee on Agriculture, Conservation and Natural Resources. VDH has recently revised its guidelines, lowering the concentration of PCBs in fish for issuance of consumption advisories. The new guidelines will become effective July 1, 2004.

Rationale for the Revision of Guidelines

Until 1998, VDH used the U.S. Food and Drug Administration's (FDA) tolerance level of 2,000 parts per billion (ppb) of PCBs in fish as a guide in issuing fish consumption advisories. However, in 1998, staff from the U.S. Environmental Protection Agency (EPA) met with VDH and the Virginia Department of Environmental Quality (DEQ) and suggested reevaluation of the guidelines. EPA's rationale was that the FDA's tolerance level was for commercial fish distributed in interstate commerce and was not appropriate for recreational or subsistence fishers. These individuals may be at a higher risk since they consistently consume more fish from a body of water than those who consume commercially caught fish.

EPA has a difference of opinion with FDA in assessing human health risk from consumption of PCB-contaminated fish. While FDA considers less than 2,000 ppb of PCBs in fish acceptable for human consumption, EPA considers only a limited number of meals per month to be acceptable with levels as low as 50 ppb.

FDA derived its tolerance level of 2,000 ppb in the early 1980s. Prior to that FDA's tolerance level for PCBs in fish was 5,000 ppb. The risk assessment approach used by FDA was based on the assumption that human exposure to PCBs via consumption of fish would be limited to 2.7 years. It was also based upon national average fish consumption by the U.S. population which did not take into consideration a higher rate of consumption by sport or subsistence fishers.

Derivation of an acceptable intake value of a contaminant is based upon several factors and assumptions. Depending upon these assumptions, one could derive several values, which fall within an extremely wide range differing by several thousands. This is the reason why many states and federal government agencies differ in what they consider acceptable intake values.

In 1998, VDH in consultation with the Maryland Department of the Environment and the North Carolina Department of Health, derived a concentration of 600 ppb of PCBs in fish as a trigger level for issuing fish consumption advisories. This trigger level was agreed upon by EPA, by the Maryland Department of the Environment and the North Carolina Department of Health. Since then, VDH has been using the concentration of PCBs in fish at 600 ppb as a trigger level in issuing fish consumption advisories on various bodies of water in the state.

In 1999, based on VDH risk assessment, both Virginia and Maryland concurrently issued fish consumption advisories for sections of the Potomac River. However, in 2002, Maryland independently changed its risk assessment for PCBs, selecting more conservative assumptions and factors resulting in a trigger level that is more stringent than that used by VDH. Recently, the North Carolina Department of Health also revised its acceptable intake value for PCBs in fish lowering its guidance level for issuing fish consumption advisories.

Since Virginia shares its waters with Maryland and North Carolina, it would be desirable that fish consumption advisories and recommendations issued across the state lines are consistent. Therefore, VDH is revising its current guidance for the issuance of consumption advisories due to contamination of fish with PCBs. According to the revised guidance, the concentration of PCBs in fish that would trigger the issuance of advisories is being lowered by using more conservative assumptions in deriving acceptable intake values.

Characteristics of PCBs

Polychlorinated biphenyls are a group of synthetic organic chemicals that contain 209 possible individual chlorinated biphenyl compounds. These chemically related compounds are called congeners that vary in their physical and chemical properties and toxicity. PCBs are either oily liquids or solids and have no taste or smell. In general, PCBs are insoluble in water, but soluble in lipids (fat). PCBs are inert; they resist both acids and alkalis, and are stable at high temperatures. Prior to 1977, PCBs were marketed as mixtures under the trade name Aroclor, Askarel, and Therminol.

Production and Use of PCBs

PCBs were produced commercially in the United States from 1929 until 1977. PCBs were used as coolants and lubricants in capacitors, transformers, and other electrical equipment, and as hydraulic fluids. They were also used in plasticizers, surface coatings, inks, adhesives, flame retardants, pesticide applications, paints, and microencapsulation of dyes for carbonless duplicating papers. Almost all of the PCBs used in the United States were produced by the Monsanto Chemical Company in Sauget, Illinois. In response to their environmental build-up, Monsanto Chemical

Company ceased production of PCBs in 1977. EPA banned all manufacture and importation of PCBs in 1979.

Sources of PCBs in the Environment

There are no known natural sources of PCBs. Although banned in the United States from further production in 1979, PCB-containing materials still in service at the time of the ban were not required to be removed from use, and, therefore, some are still in use. PCBs have been detected in soil, surface water, air, sediment, plants, and animal tissue in all regions of the world. PCBs are highly persistent in the environment with reported half-lives in soil and sediment ranging from months to years. Because PCBs have very low solubility in water and low volatility, most PCBs are contained in sediments that serve as environmental reservoirs from which PCBs may continue to be released over a long period of time. PCBs may be mobilized from sediments if disturbed (*e.g.*, flooding, dredging). Volatilization from land and surface water is also an important source for the global distribution of PCBs. PCBs are highly lipophilic (fat soluble) and are rapidly accumulated by aquatic organisms and bioaccumulated through the aquatic food chain.

Health Effects of PCBs

Exposure to PCBs predominantly occurs through the diet, especially from fish and seafood products. Red meat, poultry, eggs, and dairy products also may be important dietary sources of PCBs. Individuals in the general population who may be exposed to higher than average levels of PCBs include recreational and subsistence fishers who routinely consume large amounts of locally caught fish, subsistence hunters who routinely consume the meat and organ tissues of marine mammals, and persons who live near hazardous waste sites contaminated with PCBs. PCBs are absorbed through the gastrointestinal tract and distributed throughout the body. Because of their lipophilic nature, PCBs tend to accumulate in fatty tissues. Greater relative amounts of PCBs are usually found in the liver, adipose tissue, skin, and breast milk. It has been shown that nursing infants absorb PCB congeners from breast milk. Offspring can also be exposed to PCBs through placental transfer.

PCB exposure is associated with a wide array of adverse health effects in experimental animals. These studies have shown toxic effects to the liver, gastrointestinal system, blood, skin, endocrine system, immune system, nervous system, and reproductive system. In addition, developmental effects and liver cancer have been reported.

Despite the variety of adverse effects observed in animals exposed to PCBs, overt adverse effects in humans have been difficult to ascertain and are not well understood. This has been attributed to the fact that in most cases, the dosages tested in animals were considerably higher than those found in occupational exposures. Also, the epidemiologic studies have been inconclusive due to multiple confounding factors, uncertain exposure estimates, and statistical limitations. Skin rashes and a persistent and severe form of acne (chloracne) have been reported following direct contact with PCBs. Laboratory studies suggest that PCBs are not likey to be genotoxic to humans.

PCBs administered in large doses orally have been shown to cause liver tumors in rats and mice. Evaluation of the animal data indicates that PCBs with 54% chlorine content induce a higher yield of liver tumors in rats than other PCB mixtures. Based on studies in experimental animals, EPA has classified PCBs as probable human carcinogens. However, epidemiological studies in workers exposed to high levels of PCBs do not suggest that PCBs cause cancer in humans.

A few recent studies suggest that PCB exposure in pregnant women, at levels significantly lower than occupational exposures, may affect physical and neurobehavioral fetal development. These studies have several methodological problems, lack a dose-response relationship, and are controversial and contradictory. Confirmation of these results is not available at this time, but studies are underway which should help to determine whether or not these reported effects are valid public health concerns.

Derivation of Acceptable Concentration of PCBs in Fish

The potential to cause cancer in humans is considered to be the most important toxic endpoint for PCBs. VDH considers the concentration at which four or more 8-oz meals per month can be consumed to be acceptable. Concentrations of PCBs below the acceptable level do not trigger the issuance of a consumption advisory. VDH used the following equation for calculating an acceptable concentration of PCBs in fish at which four 8-oz meals of fish could be consumed.

$$C = \frac{RL \times BW \times PF \times EDF \times T}{CSF \times MS \times NM}$$

Where:

C	=	Acceptable concentration in fish (milligrams/kilogram of edible fish tissue)
RL	=	Acceptable risk level for incremental increase in cancer over background incidences (10^{-5})
BW	=	Average body weight for adult human (70 kilograms)
PF	=	Preparation factor (2.0) which includes fish preparation and cooking processes (assumes 50% loss of PCBs in the final prepared fish)
EDF	=	Exposure duration factor (70 years ÷ 30 years = 2.33)
T	=	Time period (30 days/month)
CSF	=	Cancer Slope Factor, 2.0 $(\text{milligrams/kilogram/day})^{-1}$
MS	=	Average fish meal (8-oz or 0.227 kilogram)
NM	=	Number of meals per month (4)

Substituting for assumptions and factors in the equation, an acceptable concentration of 54 ppb of PCBs in fish was derived corresponding to the consumption of four meals per month and was rounded to 50 ppb. Various assumptions used in deriving the acceptable concentration are described as follows:

Risk Level (RL)

Typically for carcinogens, acceptable risk levels for incremental increase in cancer over the background incidence ranging between 10^{-3} (one additional cancer in a population of one thousand people) to 10^{-6} (one additional cancer in a population of one million people) have been used in

making risk management decisions by several regulatory agencies. EPA suggests an acceptable risk level in the range from 10^{-4} to 10^{-7} when deriving acceptable concentrations of chemical contaminants in edible fish tissue. Derivation of an acceptable concentration in fish tissue using a risk level within this range is considered conservative and protective of human health. Therefore, VDH used the risk level of 10^{-5}, or one additional cancer over the background incidence expected to be found in a population of 100,000 people, when deriving a trigger level for issuing fish consumption advisories.

Average Body Weight (BW)

A body weight of 70 kilograms for an average adult is widely accepted by many regulatory agencies for risk assessment and establishing guidelines and standards for chemical exposure.

Preparation Factor (PF)

It has been reported in the literature that fish preparation and cooking can reduce PCB levels in fish from 30% to 80%, depending on the dressing and cooking processes used. VDH used a 50% reduction (factor of 2) in its calculation to derive an acceptable concentration for PCBs.

Exposure Duration Factor (EDF)

In deriving acceptable concentrations for carcinogens, a lifetime exposure of 70 years is assumed, which is considered the worst-case scenario. This assumes that a person will live in the same geographic location for 70 years, and will consume fish contaminated at or above the level of concern during this period. The mean residential occupancy period in the U.S. population has been estimated to be between 9 and 12 years. The 95^{th} percentile residential occupancy period has been estimated to be 30 years. In 2000, VDH had used a 12-year exposure duration in its calculation, which represented a central tendency estimate of exposure length at one residence. VDH used the 95^{th} percentile occupancy period of 30 years at one residence in its revised calculation. Subsequently, a factor of 2.33 was derived ($70 \div 30 = 2.33$).

Time Period (T)

Time period of 30 days per month was used to calculate the allowable concentration of PCBs in fish.

Cancer Slope Factor (CSF)

The cancer slope factor (CSF) represents an estimated cancer potency or risk associated with a specific exposure dose. The CSF is expressed as $(\text{milligrams/kilogram body weight/day})^{-1}$. EPA has derived the cancer slope factor of 1.0 $(\text{milligram/kilogram/day})^{-1}$ as the central risk estimate for PCBs. The central slope factor is generally used to represent a typical individual's risk, and for estimating aggregate risk in a given population. VDH had used this central estimate in its 2000 guidelines. In the revised guidelines, VDH used the upper bound value of 2.0 $(\text{milligram/kilogram/day})^{-1}$ for the cancer slope factor. The upper bound value provides assurance

that the risk is not likely to be underestimated. This CSF is considered appropriate for fish ingestion, soil ingestion, dust or aerosol inhalation, and all early life exposures.

Meal Size (MS)

An average meal size of 8-oz or 0.227 kilogram was assumed in calculating the acceptable concentration of PCBs in fish.

Number of Meals (NM)

An acceptable concentration of PCBs in fish was derived assuming four 8-oz meals during a period of 30 days.

Conclusion

VDH would use 50 micrograms per kilogram or 50 ppb PCBs in edible fish tissue as the trigger level for issuance of a fish consumption advisory. VDH will use a three-tiered approach when issuing a fish consumption advisory.

- Average fish tissue concentrations of PCBs ranging from non-detectable to below 50 ppb will not warrant issuance of a fish consumption advisory.

- When the average concentrations of PCBs in fish tissue range from >50 ppb to 500 ppb, VDH would recommend limiting consumption of contaminated species to one or two, 8-oz meals per month.

- When the average concentrations of PCBs in fish tissue exceed 500 ppb, VDH would recommend that contaminated fish should not be consumed.

VDH would also recommend that pregnant women, women of child-bearing age, nursing mothers, infants, and young children should avoid or limit eating PCB-contaminated fish from the advisory area.

VDH will issue fish consumption advisories using the above guidelines based on DEQ's determination that a segment of a water body is impaired due to PCBs. DEQ uses 54 ppb as the screening value in its water quality assessment.

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