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VIRGINIA DEPARTMENT OF HEALTH GUIDELINES FOR ISSUANCE OF FISH CONSUMPTION ADVISORIES DUE TO CONTAMINATION OF FISH WITH POLYCHLORINATED BIPHENYLS (REVISED 2012)

Pursuant to § 32.1-248.01, Code of Virginia, the Virginia Department of Health (VDH) "...shall develop a written policy, which shall be revised annually, that identifies the criteria and levels of concern for certain toxic substances that the Department will use in determining whether to issue a fish consumption advisory..." VDH currently maintains fish consumption guidelines for five fish contaminants, including dioxin, kepone, mercury, polychlorinated biphenyls (PCBs), and polybrominated diphyenyl ethers. PCBs were included in the initial guidelines developed in 2000 because they persist in the environment, bioaccumulate in the food chain, are associated with skin conditions in adults, neurobehavioral and immunological changes in children, and are known to cause cancer in animals. VDH has recently revised its guidelines for calculating the concentration of PCBs in fish for issuance of consumption advisories. The new guidelines will become effective November 1, 2012.

Rationale for the Revision of Guidelines

Previous PCBs guidelines drafted in 2000 and 2004 for consumption of fish were developed pursuant to § 32.1-248.01, Code of Virginia. At that time, VDH derived acceptable intake values of contaminants in fish based upon several factors and assumptions from regulatory and non-regulatory state and federal agencies including the Food and Drug Administration and the Environmental Protection Agency (EPA). The EPA recently released new factors and assumptions related to human behavior and characteristics that can be used to determine an individual's exposure to a contaminant. Exposure factors to consider include length of exposure, frequency of exposure, and population characteristics such as body weight, and amount of fish consumed during a meal. Depending upon these assumptions, one could derive several values, which fall within an extremely wide range differing by several orders of magnitude. This is the reason why many states and federal government agencies differ in what they consider acceptable intake values.

After reviewing the updated factors and assumptions recommended by EPA, new factors adopted by VDH to calculate the acceptable concentration of PCBs in fish for consumption include body weight, life expectancy, and how long an individual lives at the same residence. VDH will now use 80 kg for the average adult body weight instead of 70 kg. The exposure duration factor (EDF) will also change. The EDF is the ratio of life expectancy to how long an individual lives at the same residence. Previously, VDH used 70 years for life expectancy and 30 years for the length an individual would be expected to live at the same residence to give an EDF = 2.33 (70 ÷ 30 = 2.33). VDH now uses 78 years for the life expectancy and 32 years for the length of time an individual would be expected to live in the same residence. This produces an EDF = 2.44 (78 ÷ 32 = 2.44). This change is

considered health protective because it assumes that an individual will live to be 78 years old, live at the same residence for 32 years, and consume fish monthly from the body of water where the consumption advisory is in place. Lastly, to be consistent with the other VDH fish consumption guidelines that use two meals per month, VDH will use two fish meals per month when calculating the acceptable concentration of PCBs in fish, whereas 4 meals per month was used previously.

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, which 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 names 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. Because PCBs persist in the environment, 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 formula for calculating an acceptable concentration, corresponding to a recommended two meals per month of PCBs in edible fish tissue, for protecting fish consumers from potential carcinogenic effects is as follows:

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

Where:

C = Acceptable concentration of PCBs in edible portion of fish in milligrams per kilograms (mg/kg)

RL = Acceptable risk level for incremental increase in cancer over the background incidence (10^{-5}; or one additional cancer in a population of 100,000 people)

BW = Average consumer adult body weight in kilograms (80 kg)

PF = Preparation factor (2.0) which includes fish preparation and processes; assuming a 50% loss of PCBs

EDF = Exposure duration factor (78 years ÷ 32 years = 2.44)

T = Time period 30 days (days/month)

CSF = Cancer slope factor of 2 milligrams per kilograms per day $(mg/kg/day)^{-1}$

MS = Average fish meal size of 8 ounces (oz) or 0.227 kg

NM = Number of allowable meals per month (2 meals/month)

Substituting for assumptions and factors in the equation, an acceptable concentration of 128 ppb of PCBs in edible fish tissue was calculated and rounded to 100 ppb.

$$C = \frac{1x10^{-5} \text{ x } 80 \text{ kg x } 2 \text{ x } 2.44 \text{ x } 30 \text{ day/month}}{2.0 \text{ (mg/kg/day)}^{-1} \text{x } 0.227 \text{ kg/meal x } 2 \text{ meals/month}} = .128 \sim .100 \text{ mg/kg or } 100 \text{ ppb}$$

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^{-6} 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.

Body Weight (BW)

The average adult body weight is widely accepted by many regulatory agencies for risk assessment and establishing guidelines and standards for chemical exposure. The current average adult body weight is 80 kg.

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 78 years is assumed, which is considered the worst-case scenario and is consistent with the EPA's 2011 revised guidelines. This assumes that a person will live in the same geographic location for 78 years, and will consume fish contaminated at or above the level of concern during this period. In 2004, VDH had used a 30-year exposure duration in its calculation, which represented the 95th percentile. VDH will now use the revised 90th percentile residential occupancy period of 32 years at one residence in its calculation. Subsequently, an exposure duration factor of 2.44 was derived (78 ÷ 32 = 2.44).

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 (milligrams/kilogram body weight/day)$^{-1}$. EPA has derived the cancer slope factor of 1.0 (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 (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)

Meal size is defined as the amount of fish (in kilograms) consumed at one meal. An 8-oz (0.227 kg) meal size was assumed.

Number of Meals (NM)

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

Conclusion

VDH would use 100 micrograms per kilogram or 100 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 100 ppb will not warrant issuance of a fish consumption advisory.
- When the average concentrations of PCBs in fish tissue range from 100 ppb to below 500 ppb, VDH recommends limiting consumption of contaminated species to two, 8-oz meals per month.
- When the average concentrations of PCBs in fish tissue equal or exceed 500 ppb, VDH recommends that contaminated fish should not be consumed.

VDH also recommends that pregnant women, women of child-bearing age, nursing mothers, infants, and young children should not consume 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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