COMMONWEALTH of VIRGINIA

Department of Health

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Annual Policy Review of Criteria and Levels of Concern for Certain Toxic Substances Used in Determining Whether to Issue a Fish Consumption Advisory

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 (PCB), and polybrominated diphyenyl ethers (PBDE). VDH has recently revised its guidelines for calculating the concentration of dioxin, mercury, PCB, and PBDE in fish for issuance of consumption advisories. The new guidelines will become effective November 1, 2012.

In July 2012, VDH reviewed the current guidelines and applicable science related to PCB, PBDE, mercury, dioxin, and Kepone and determined that an update to the current fish consumption advisory guidelines is indicated at this time. The revised advisory guidelines are intended to reduce exposure to contamination in the edible portion of certain fish species found in Virginia's waters. Below is the current list of contaminants and recommended concentrations in the edible fish portion which prompt a fish consumption advisory in Virginia.

PCB – Average fish tissue concentrations of PCBs ranging from non-detectable to below 100 parts per billion (ppb) will not warrant issuance of a fish consumption advisory. When the average concentrations of PCBs in fish tissue range from >100 ppb to 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 exceed 500 ppb, VDH recommends that contaminated fish should not be consumed.

PBDE – Average fish tissue concentrations ranging from non-detectable to below 0.5 ppm will not warrant issuance of a fish-eating advisory. When the average concentrations in fish range from 0.5 ppm to below 1.0 ppm, VDH recommends limiting consumption of contaminated species to two 8-oz meals per month. When the average concentrations in fish exceed 1.0 ppm, VDH recommends that contaminated fish should not be consumed.

Mercury – Average fish tissue concentrations ranging from non-detectable to below 0.5 ppm will not warrant issuance of a fish-eating advisory. When the average concentrations in fish range from 0.5 ppm to below 1 ppm, VDH recommends limiting consumption of contaminated species to two, 8-oz meals per month. When the average concentration in fish range from 1 ppm to below 2.0 ppm, VDH recommends limiting consumption of contaminated species to one, 8-oz meal per month. When the average concentrations in fish exceed 2.0 ppm, VDH recommends that contaminated fish should not be consumed.

Dioxin – Average fish tissue concentrations of TCDD ranging from non-detectable to below 2 parts per trillion (ppt) will not warrant issuance of a fish-eating advisory. When the average concentrations of TCDD in fish range from 2 ppt to below 5 ppt, VDH recommends limiting consumption of contaminated species to two, 8-oz meals per month. When the average concentrations of TCDD in fish range from 5 ppt to below 10 ppt, VDH recommends limiting consumption of contaminated species to one, 8-oz meal per month. When the average concentrations in TCDD in fish exceed 10 ppt, VDH recommends that contaminated fish should not be consumed.

Kepone – VDH is currently using the U.S. Food and Drug Administration action level of 0.3 mg/kg. When Kepone levels in fish are 0.3 mg/kg or higher, VDH recommends avoiding consumption of contaminated fish species.

VDH also recommends that pregnant women, women of child-bearing age, nursing mothers, infants, and young children should not consume contaminated fish from an advisory area.

The next annual review of Virginia’s guidelines for issuance of fish consumption advisories due to contamination of fish will be conducted in July 2013.

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July 31, 2012

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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 ($70 \div 30 = 2.33$). 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 ($78 \div 32 = 2.44$). 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.

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 ($78 \div 32 = 2.44$).

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 $(\text{milligram/kilogram/day})^{-1}$ 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)

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 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 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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July 31, 2012

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VIRGINIA DEPARTMENT OF HEALTH GUIDELINE FOR ISSUANCE OF FISH-EATING ADVISORY DUE TO CONTAMINATION OF FISH WITH POLYBROMINATED DIPHENYL ETHERS (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, and polybrominated diphyenyl ethers (PBDEs). Warnings against eating fish that may be contaminated with PBDEs were included in the initial guidelines developed in 2000 because PBDEs persist in the environment, bioaccumulate in the food chain, and have been shown to be produce kidney, liver, thyroid, and developmental toxicity. VDH has recently revised its guidelines for calculating the concentration of PBDEs in fish for issuance of consumption advisories. The new guidelines will become effective November 1, 2012.

Rationale for the Revision of Guidelines

Previous PBDEs guidelines drafted in 2000 and revised in 2010 for consumption of fish were developed pursuant to § 32.1-248.01, Code of Virginia. At that time, VDH derived acceptable intake values of a contaminant in fish based upon several factors and assumptions from regulatory and non-regulatory 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. For this reason, many states and federal government agencies differ in what they consider acceptable intake values.

After reviewing the updated factors and assumptions recommended by EPA, the only updated factor adopted by VDH for calculating the acceptable concentration of PBDEs in fish for consumption was the average adult body weight. VDH will now use 80 kg for the average adult body weight instead of 70 kg.

Characteristics of PBDEs

PBDEs are dicyclic aromatic ethers that are formed by the bromination of diphenyl oxide. Computers, textiles, and electronic components are treated with PBDEs to retard their combustibility. During a fire PBDEs utilize vapor phase chemical reactions that interfere with the combustion process resulting in delaying ignition and the spread of fire. PBDEs have a common structure of a brominated diphenyl ether molecule. There are 209 possible PBDE compounds depending on the location and number of bromine atoms on the diphenyl ether molecule; each are termed congener and are assigned a specific brominated diphenyl ether (BDE) number. PBDEs are closely related to polychlorinated biphenyls in their chemical, physical, and, environmental properties. PBDEs are virtually insoluble in water, soluble in fat, and vary in solubility in various organic solvents. PBDEs are resistant to breakdown in the environment and tend to bioaccumulate in the food chain. Because PBDEs are persistent in the environment and can bioaccumulate in fish, a criteria or level of concern was developed for issuing a fish advisory when PBDEs are detected in fish.

Production and Use of PBDEs

PBDEs have been marketed in three primary formulations: penta, octa, and deca formulation. The formulations differ in their composition of BDE congeners. The dominant congeners in pentaBDE are BDE-99 (35−50%) and BDE-47 (25−37%). The octa formulation is composed of primarily BDE-183 (40%) and BDE-197 (21%), and the deca formulation is dominated by BDE-209 (97.5%). The total annual market demand worldwide for PBDE in 2001 was estimated at roughly 149 million pounds. Technical decabromodiphenyl ether (decaBDE) accounted for 83% of total world production while technical mixtures of octaBDE and pentaBDE were 6% and 11% of the total demand, respectively.

The penta and octa formulations were voluntarily withdrawn from the U.S. marketplace by their manufacturers at the end of 2004, leaving only the deca formulation for use in commercial products in the United States. In December of 2009, the EPA announced the phase out of decaBDE, with production, importation, and sales of decaBDE to end by 12/31/2012 for most uses in the United States, and for all uses to end by 12/31/2013. PBDEs are currently used as flame retardant additives in polymers, textiles, plastics, coatings, and electrical components found in common goods including computers, televisions, and other electrical appliances.

Sources of PBDEs in the Environment

Although PBDEs have not been reported to occur naturally in the environment, worldwide use of PBDEs has resulted in the presence of lower brominated congeners such as tetraBDE and pentaBDE in the environment. Higher brominated congeners, for example, octaBDE and decaBDE tend to concentrate near point sources. Even though the penta formulations has been withdrawn from the U.S. market, past use and possible debromination of higher-brominated congeners by photolytic or biological mechanisms might result in the continued presence of these lower-brominated congeners in humans and the environment.

PBDEs are lipophilic and hydrophobic compounds and readily bioaccumulate into terrestrial and aquatic food chains. PBDEs in the environment were first identified in sediments in the United States in 1979 and in fish from Sweden in 1981. In most fish BDE-47 is the major congener contributing to total body burden of PBDEs. The congener distribution in tissues of fish usually follows the order BDE-47 > BDE-99 > BDE-100 > BDE-154 > BDE-153 > BDE-49 > BDE-28.

Toxicity of PBDEs

No studies are available on the toxicity of PBDEs in humans. Studies have been conducted in laboratory animals to gain a better understanding of the potential health risks of PBDEs. In general, PBDEs have low acute oral toxicity in experimental animals. Animal studies have suggested potential concerns about liver toxicity, thyroid toxicity, developmental and reproductive toxicity, and developmental neurotoxicity. Studies of the carcinogenic potential of some PBDEs have been reviewed as part of EPA's IRIS 2008 toxicological review. EPA has found that the data for decaBDE support a finding of "suggestive evidence of carcinogenic potential," and has found that the data support a finding of "inadequate information to assess carcinogenic potential" for congeners BDE-99, BDE-153, and BDE-47. Based on current animal toxicological information the EPA has developed an RfD = 0.0001 mg/kg/day for BDE-47. The RfD is an estimate of a daily exposure to the human population (including sensitive subpopulations) that is likely to be without appreciable risk of deleterious effects during a lifetime.

Derivation of Acceptable Concentration of PBDEs in Fish

The formula for calculating an acceptable concentration corresponding to a recommended two meals per month of PBDEs in edible fish tissue for protecting fish consumers from non-cancer health effects is as follows:

$$C = \frac{RfD \times BW \times T}{MS \times NM}$$

Where:

C = acceptable concentration of PBDE in edible portions of fish in milligrams per kilograms (mg/kg)

RfD = reference dose for BDE-47 in milligrams per kilogram per day (0.0001 mg/kg/day)

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

T = time period 30 day (days/month)

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

NM = number of allowable fish meals per month (2 meals/month)

Substituting for assumptions in the above equation, an acceptable PBDE concentration of 0.5 mg/kg in edible fish tissue was calculated:

$$C = \frac{0.0001 \text{ mg/kg/day} \times 80 \text{ kg} \times 30 \text{ day/month}}{0.227 \text{ kg/meal} \times 2 \text{ meals/month}}$$

$$= 0.528 \text{ mg/kg} \approx 0.5 \text{ mg/kg} = 0.5 \text{ ppm}$$

Various assumptions used in deriving the acceptable concentration are described as follows:

Concentration (C)

Acceptable concentrations of PBDE (mg/kg) in edible portions of fish tissue.

Reference Dose (RfD)

The RfD is an estimate of a daily exposure to the human population (including sensitive subpopulations) that is likely to be without appreciable risk of deleterious effects during a lifetime.

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.

Time (T)

Time period (30 day/month) was used to calculate fish meal consumption limits in a 30-day period as a function of meal size.

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)

Number of meals consumption limit is expressed as the maximum allowable fish meals in a 30-day time period (meals/month). These are based on the total dose allowable over a 1-month period (based on the RfD).

Conclusion

Based on the above calculation, VDH would use 0.5 mg/kg or 0.5 parts per million (ppm) PBDE in fish as the trigger level for issuance of a fish-eating advisory. VDH will use a three-tiered approach when issuing a fish-eating advisory.

- Average fish tissue concentrations ranging from non-detectable to below 0.5 ppm, will not warrant issuance of a fish-eating advisory.
- When the average concentrations in fish range from 0.5 ppm to below 1.0 ppm, VDH recommends limiting consumption of contaminated species to two 8-ounce (oz) meals per month.
- When the average concentrations in fish exceed 1.0 ppm, VDH recommends that contaminated fish should not be consumed.

Reproductive and developmental effects of PBDEs have not yet been fully evaluated; therefore, it would be prudent for sensitive populations, such as pregnant women, nursing to avoid consuming PBDE-contaminated fish from the advisory area.

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VIRGINIA DEPARTMENT OF HEALTH GUIDELINE FOR ISSUANCE OF FISH-EATING ADVISORY DUE TO CONTAMINATION OF FISH WITH MERCURY (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, and polybrominated diphyenyl ethers. Mercury was included in the initial guidelines developed in 2000 because mercury persist in the environment, bioaccumulate in the food chain, affects the nervous system, and can permanently damage the brain, kidneys, and developing fetus at high exposure levels. VDH has recently revised its guidelines for calculating the concentration of mercury in fish for issuance of consumption advisories. The new guidelines will become effective November 1, 2012.

Rationale for the Revision of Guidelines

Previous mercury guidelines drafted in 2000 for consumption of fish were developed pursuant to § 32.1-248.01, Code of Virginia. At that time, VDH derived acceptable intake values of a contaminant 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. For this reason, several states and federal government agencies differ in what they consider acceptable intake values.

After reviewing the updated factors and assumptions recommended by EPA, the only updated factor adopted by VDH for calculating the acceptable concentration of mercury in fish for consumption was the average adult body weight. VDH will now use 80 kg for the average adult body weight, whereas 70 kg was used previously.

Characteristics of Mercury

Mercury is a naturally occurring metal which is widespread and persistent in the environment. It exists in three forms: elemental or metallic mercury, inorganic mercury, and organic mercury.

Elemental mercury is a silver-white liquid at room temperature that vaporizes readily when heated. Inorganic mercury compounds occur when mercury combines with elements such as chlorine, sulfur, or oxygen. Most inorganic compounds are powders or crystals. Organic mercury compounds occur when mercury combines with carbon. One organic form of mercury, methylmercury, is produced when a carbon and three hydrogen molecules are attached to the elemental mercury. Methylmercury is of particular concern because it can accumulate up the food chain in aquatic systems and lead to high concentrations in predatory fish which may be caught and eaten.

Uses of Mercury

Elemental mercury is used in thermometers, thermostats, switches, barometers, batteries, dental amalgam, and other products. Inorganic mercury compounds are commonly used in electrical equipment (e.g., switches and lamps), and in medicinal and skin care products, such as antiseptic creams and ointments. Organic mercury compounds are used in industry as pigments in paints and as fungicides.

Sources of Mercury in the Environment

Mercury is released to the environment by both natural sources and human activities. Most of the mercury in air, water, and soil is inorganic mercury. This inorganic mercury can enter the air from deposits of ore that contain mercury, from burning fuels or garbage, and from emissions by factories that use mercury. Inorganic mercury may also enter water or soil from rocks that contain mercury, releases of water containing mercury from factories or water treatment facilities, and the disposal of wastes. Organic compounds of mercury may be released in the soil through the use of mercury-containing fungicides. Metallic mercury can evaporate easily into the air and be carried a long distance before returning to water or soil in rain or snow. Once mercury enters lakes, rivers, or oceans in any form, it is converted to methylmercury by microorganisms (bacteria and fungi) or by chemical reactions.

Fish absorb methylmercury directly from water and from eating smaller aquatic organisms that contain methylmercury. Although virtually all fish species contain at least trace amounts of methylmercury, larger predatory fish species have the highest concentrations. Methylmercury is tightly bound to proteins in all fish tissue, including muscle. There is no method of cooking or cleaning fish which will reduce the amount of mercury in a meal. Since almost all of the mercury in fish is in the form of methylmercury, the fish-eating advisory guideline is based on methylmercury.

Toxicity of Mercury

Evidence from human and animal studies indicates that the nervous system is sensitive to all forms of mercury. Exposure to high levels of all forms of mercury can permanently damage the brain, kidney, and developing fetus. Methylmercury is more harmful because more mercury in this form reaches the brain. Methylmercury is rapidly absorbed from the gastrointestinal tract (about 95%) and readily enters the adult and fetal brain where it accumulates and slowly converts to inorganic mercury. The exact mechanism by which mercury causes neurotoxic effects is not known, and data are not avail-available on how exposure to other forms of mercury affects methylmercury toxicity.

Acute high-dose exposure to methylmercury can result in adverse effects in several organ systems throughout the life span of humans and animals. Extensive data exist on the effects of methylmercury on the development of the brain in humans and animals. The most severe effects reported in humans were seen following high-dose acute poisoning episodes in Japan and Iraq. The outbreak of neurological dis- orders in Japan in the 1950s was attributed to the consumption of fish contaminated with methylmercury. Industrial waste containing inorganic mercury had been discharged into Minimata Bay and was converted by microorganisms into methylmercury. This resulted in contamination of fish, a major food source to the surrounding population. In this incident 700 people died and approximately 9,000 suffered severe health effects. A similar epidemic of neurological disorders occurred in Iraq in 1971 as a result of con- sumption of contaminated food. In this case, flour was ground from grain treated with methylmercury fungicide. This incident affected more than 6,000 people. The health effects on brain functioning included irritability, mental retardation, shyness, tremors, cerebral palsy, deafness, and blindness in individuals who were exposed in utero, and sensory and motor impairment in exposed adults.

Chronic, low-dose prenatal methylmercury exposure from maternal consumption of fish has been associated with more subtle endpoints of neurotoxicity in children. Results from the three large epidemiological studies (the Faroe Islands, Seychelles Islands, and New Zealand studies) have added substantially to the body of knowledge on brain development following long-term exposure to small amounts of methylmercury. The Faroe Islands study reported associations between low-dose prenatal methylmercury exposure and children's performance on standardized neurobehavioral tests, particularly on the tests of attention, fine motor functions, confrontational naming, visual-spatial abilities (e.g., drawing), and verbal memory. The Seychelles Islands study did not report such associations. The New Zealand study also observed associations, as did the large pilot study conducted in the Faroe Islands.

There is evidence in humans and animals that exposure to methylmercury can have adverse effects on the developing and adult cardiovascular system (blood pressure regulation, heart rate variability, and heart disease). There is also evidence in animals that the immune and reproductive systems are sensitive targets for methylmercury. In 2000, the National Academy of Sciences (NAS) recommended a methylmercury reference dose (RfD) of 0.0001 milligrams per kilograms per day (mg/kg/day). The RfD is an estimate of a daily exposure to the human population (including sensitive subpopulations) that is likely to be without appreciable risk of deleterious effects during a lifetime.

Derivation of Acceptable Concentration of Methylmercury in Fish

The formula for calculating an acceptable concentration, corresponding to a recommended two meals per month of methylmercury in edible fish tissue, for protecting fish consumers from non-cancer health effects is as follows:

$$C = \frac{RfD \times BW \times T}{MS \times NM}$$

Where:

C = acceptable concentration of methylmercury in edible portions of fish in milligrams per kilograms (mg/kg).

RfD = reference dose (RfD) for methylmercury in milligrams per kilogram per day (0.0001 mg/kg/day).

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

T = time period 30 days (days/month).

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 in the above equation, an acceptable methylmercury concentration of 0.5 mg/kg or 0.5 ppm in edible fish tissue was calculated:

$$C = \frac{0.0001 \text{ mg/kg/day} \times 80 \text{ kg} \times 30 \text{ day/month}}{0.227 \text{ kg/meal} \times 2 \text{ meals/month}}$$

$$= 0.528 \text{ mg/kg} \approx 0.5 \text{ mg/kg} = 0.5 \text{ ppm}$$

Various assumptions used in deriving the acceptable concentration are described as follows:

Concentration (C)

Acceptable concentration of methylmercury (mg/kg) in edible portions of fish tissue.

Reference Dose (RfD)

The RfD is an estimate of a daily exposure to the human population (including sensitive subpopulations) that is likely to be without appreciable risk of deleterious effects during a lifetime.

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.

Time (T)

Time period (30 day/month) was used to calculate fish meal consumption limits in a 30-day period as a function of meal size.

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)

Number of meals consumption limit is expressed as the maximum allowable fish meals in a 30-day time period (meals/month). These are based on the total dose allowable over a 1-month period (based on the RfD).

Conclusion

Based on the above calculation, VDH would use 0.5 mg/kg or 0.5 ppm of methylmercury in fish as the trigger level for the issuance of a fish-eating advisory. VDH will use a four-tiered approach when issuing a fish-eating advisory.

- Average fish tissue concentrations ranging from non-detectable to below 0.5 ppm will not warrant issuance of a fish-eating advisory.
- When the average concentrations in fish range from 0.5 ppm to below 1 ppm, VDH recommends limiting consumption of contaminated species to two, 8-oz meals per month.

- When the average concentration in fish range from 1 ppm to below 2.0 ppm, VDH recommends limiting consumption of contaminated species to one, 8-oz meal per month.
- When the average concentrations in fish exceed 2.0 ppm, VDH recommends that contaminated fish should not be consumed.

VDH also recommends that pregnant women, nursing mothers, and young children should not consume fish contaminated with methylmercury at concentrations above 0.5 ppm.

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July 31, 2012

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VIRGINIA DEPARTMENT OF HEALTH GUIDELINE FOR ISSUANCE OF FISH-EATING ADVISORY DUE TO CONTAMINATION OF FISH WITH DIOXIN (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, and polybrominated diphyenyl ethers. Dioxin was included in the initial guidelines developed in 2000 because dioxin persists in the environment, bioaccumulates in the food chain, and has been shown to cause acne-like skin lesions in humans, reproductive damage and birth defects in animal studies, and may reasonably be anticipated to cause cancer in humans. VDH has recently revised its guidelines for calculating the concentration of dioxin in fish for issuance of consumption advisories. The new guidelines will become effective November 1, 2012.

Rationale for the Revision of Guidelines

Previous dioxin guidelines drafted in 2000 for consumption of fish were developed pursuant to § 32.1-248.01, Code of Virginia. At that time VDH derived acceptable intake values of a contaminant is 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 assumption 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 dioxin 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 12 years for the average length of time an individual would be expected to live at the same residence to give an EDF = 5.8 (70 ÷ 12 = 5.8) for dioxin. VDH will now use 78 years for 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 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 effect.

Characteristics of Dioxin

"Dioxin" is the common name used to describe a single chemical or mixture of chemicals known as chlorinated dibenzo-para-dioxins (CDDs). There are 75 individual compounds (congeners) that differ in the number and position of attached chlorine atoms to a molecule of CDD. These chemically and structurally related compounds vary in their physical and chemical properties and toxicity. The most common congener 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD) is one of 75 possible CDD compounds. This compound, often called simply dioxin, represents the reference compound for the dioxin family. It is one of the most toxic of the CDDs and is the one most studied. TCDD is colorless, odorless, lipid-soluble, and only sparingly soluble in water. TCDD is susceptible to photodegradation in the presence of ultraviolet light. TCDD is of particular concern because of its persistence in the environment, its high bioaccumulation potential in the food chain, and its toxic potency in experimental animals.

Production and Use of TCDD

TCDD is an unwanted impurity during the manufacture of certain organic compounds such as herbicides containing 2,4,5-T or 2,4,5-trichlorophenoxy acid; 2,4,5-trichlorophenol; pentachlorophenol; hexachlorophene; and polychlorinated biphenyls. TCDD is introduced in the environment from the incomplete combustion of organic materials by forest fires or volcanic activity. TCDD is also produced from cigarette smoke, from the burning of fuels, wood, and wastes, and from chlorine bleaching processes used in pulp and paper mills. At present, TCDD is synthesized only on a laboratory scale, where it is used as a research chemical.

Sources of TCDD in the Environment

In the environment, TCDD has been found throughout the world in practically all media including air, soil, water, sediment, fish and shellfish, and in other food products such as meat and dairy products. The highest levels of these compounds are found in soils, sediments, and biota; very low levels are found in water and air. TCDD enters the ecological food web by being deposited from the atmosphere, either directly following air emissions or indirectly by processes that return TCDD already in the environment to the atmosphere. Once TCDD reaches the environment, it is highly persistent and can bioaccumulate in the tissues of animals.

Toxicity of TCDD

EPA estimates that most TCDD exposure occurs through the diet, with over 95% of TCDD intake for a typical person coming through the dietary intake of contaminated animal fats and fish. Small amounts of exposure occur from breathing air containing trace amounts of TCDD on particles or in vapor form, inadvertent ingestion of soil containing TCDD, and from skin absorption of air, soil, or water containing minute levels.

TCDD is well absorbed through the gastrointestinal tract, respiratory tract, and skin, and distributed throughout the body. The most noted health effect in humans exposed to large amounts of TCDD via direct skin contact is chloracne. Chloracne is a severe acne-like condition, which can persist for many years, and usually appears on the face and upper trunk area. For many individuals, the condition disappears after discontinuation of exposure. Although chloracne is a known symptom of dermal exposure, it is believed that it may also develop following TCDD exposure by any route. Other skin effects noted in humans exposed to high doses of TCDD include skin rashes, discoloration, and excessive body hair.

TCDD is highly toxic to many animal species. In certain animal species, TCDD is especially harmful and can cause death after a single exposure. Exposure to lower levels of TCDD results in a wide variety of effects in experimental animals, including weight loss; liver damage; disruption of the endocrine system; suppression of the immune system; adverse effects on reproduction and development; chloracne; and cancer. EPA characterizes TCDD as a " probable human carcinogen" based on the weight of animal and human studies. The most well-known toxic endpoint for TCDD is its potential for cancer in humans based on studies in experimental animals.

Derivation of Acceptable Concentrations of TCDD in Fish

The formula for calculating an acceptable concentration, corresponding to a recommended two meals per month of TCDD 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 TCDD 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 TCDD
- EDF = Exposure duration factor (78 years $\div$ 32 = 2.44)
- T = Time period 30 days (days/month)
- CSF = Cancer slope factor of 156,000 in 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 above equation, an acceptable concentration of 1.6 parts per trillion (ppt) of TCDD in edible fish tissue was calculated and rounded to 2 ppt:

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

It has been reported in the literature that fish preparation and cooking can reduce TCDD levels in fish by approximately 50% on average. VDH has used a 50% reduction (factor of 2) in its risk assessment calculations.

Exposure Duration Factor (EDF)

In risk assessment calculations 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 all of the fish consumed will be contaminated at or above the same level of contamination. 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 will now use the revised 90^{th} percentile residential occupancy period of 32 years in its calculation. Subsequently, an exposure duration factor of 2.44 was derived (78 ÷ 32 = 2.44).

Time (T)

Time period of 30 days/month was used to calculate fish meal consumption limits, in a 30-day period as a function of meal size.

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 $(\text{milligrams/kilogram body weight/day})^{-1}$. The CSF of 156,000 $(\text{mg/kg/d})^{-1}$ derived by the EPA for TCDD was used for this risk assessment.

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)

Number of meals consumption limit is expressed as the maximum allowable fish meals in a 30-day time period. These are based on the total dose allowable over a 1-month period.

Conclusion

Based on the above calculation, VDH would use 2 ng/kg or 2 ppt TCDD in fish as the trigger level for issuance of a fish-eating advisory. When individual fish data are available, 50% of fish samples should exceed the guidance levels in order to trigger an advisory. VDH will use a four-tiered approach when issuing a fish-eating advisory.

- Average fish tissue concentrations of TCDD ranging from non-detectable to below 2 ppt will not warrant issuance of a fish-eating advisory.

- When the average concentrations of TCDD in fish range from 2 ppt to below 5 ppt, VDH recommends limiting consumption of contaminated species to two, 8-oz meals per month.

- When the average concentrations of TCDD in fish range from 5 ppt to below 10 ppt, VDH recommends limiting consumption of contaminated species to one, 8-oz meal per month.

- When the average concentrations in TCDD in fish exceed 10 ppt, 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 avoid eating any fish from the advisory area, since TCDD may have a greater effect on developing organs in young children or in the fetus.

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July 30, 2012

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