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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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July 31, 2012

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