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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 ÷ 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:

$$C = \frac{1x10^{-5} \text{ x } 80 \text{ kg x } 2 \text{ x } 2.44 \text{ x } 30 \text{ day/month}}{156{,}000 \text{ (mg/kg/day)}^{-1} \text{x } 0.227 \text{ kg/meal x } 2 \text{ meals/month}} = 1.65x10^{-6} \text{mg/kg} \approx 2 \text{ ppt}$$

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 ($78 \div 32 = 2.44$).

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 equal or 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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