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December 1, 2000

Joseph A. Levitt  
Director, Center for Food Safety and Applied Nutrition  
Food and Drug Administration  
200 C. Street, S.W.  
Washington, DC, 20204

Dear Mr. Levitt:

I am writing in response to your letter dated November 9, 2000 requesting clarification of two statements in *The Toxicological Effects of Methylmercury*. The two statements you cited are:

“Available consumption data and current population and fertility rates indicate that over 60,000 newborns annually might be at risk for adverse neurodevelopmental effects from in utero exposure to MeHg” (page 325);  
and

“The committee estimates that over 60,000 children are born each year at risk for adverse neurodevelopmental effects due to in utero exposure to MeHg”  
(page 327).

You requested clarification on the derivation of the “60,000” figure, and what the term “at risk” means. I consulted with Drs. Thomas Burke and Alan Stern for the explanation of the calculation, and the entire committee has seen and concurs with the content of the letter.

Attached is a table showing the annual number of newborns born at mercury levels that place them at risk for adverse effects from methylmercury. Details of and assumptions used in the calculation are also attached. Individuals in the top 5% of methylmercury exposure are of concern because, as can be seen in Table 8-3 of the committee’s report, those individuals are exposed to methylmercury at levels above the current RfD, and with a margin of exposure (MOE) generally less than 10. In addition, both WHO and EPA have also found 5% of the population to be of concern because of fish consumption levels. The number of infants born to those women is calculated based on census data and birth rates. It should be noted that the calculation was done using exposure data available at the time of the report, and that the committee did recommend that reliable data on exposure, possibly the NHANES IV data, be examined

when it becomes available.

The term "at risk" refers to children born each year from mothers with a level of methylmercury that is above the current RfD. (Note that the subcommittee concluded that the level of EPA's RfD is scientifically justifiable.) The offspring of those mothers are exposed to mercury levels that are not considered safe, and, therefore, the committee considered them to be "at risk". The calculation presents an estimate of the number of children at risk because of high exposure (maternal dose exceeding current RfD). That number should not be interpreted as an estimate of the annual number of cases of adverse neuro-developmental effects. The committee does not believe it is possible to estimate a meaningful number of children that might be affected within the at risk population. It should be noted that there is presently no established NOAEL (no observed adverse effect level for methyl mercury). Therefore, there may be some increased risk above population background levels to developing infants exposed to levels below the 95 percentile. These infants are not included in the 60,000.

We hope this clarifies the derivation and meaning of the 60,000 children at risk.

Sincerely,



Robert Goyer  
Chair, Committee on the Toxicological Effects of Mercury

Enclosure (2)

cc: Dr. James Reisa  
Dr. Michelle Catlin

### Annual Number of Newborns at High Exposure Risk

U.S. population of women aged 15 to 44 years	60,208,000
Percent reporting fish consumption	30.5 Percent
Female fish consumers aged 15 to 44 years	18,363,440
Population of concern (highest 5% exposed, consume 100g fish/day)	918,172
Birth rate for women 15-44	65.6 per 1000
Annual number of newborns at high exposure risk	60,232

<sup>a</sup> Population Estimates Program, U.S. Census Bureau, POP@CENSUS.GOV  
December 23, 1999

<sup>b</sup> Continuing Surveys of Food Intake by Individuals, 1989/1990

<sup>c</sup> National Center for Health Statistics, National Vital Statistics Report, Vol. 48, No. 3,  
March 2000

## Methodology and Assumption Used in the Calculation of Annual Number of Newborns at High Exposure Risk

Newborns at risk = (Number of U.S. women aged 15 to 44 years) x (Percent of U.S. population reporting fish consumption) x (Individuals with the top 5% of mercury exposure) x (Birth rate for women aged 15 to 44 years)

$$= (60,208,000)^a \times (30.5\%)^b \times (5\%)^c \times (65.6 \text{ per } 1,000)^d$$

$$= 60,232 \text{ newborns at risk}$$

<sup>a</sup> From Population Estimates Program, U.S. Census Bureau, POP@CENSUS.GOV December 23, 1999

<sup>b</sup> From Continuing Surveys of Food Intake by Individuals, 1989/1990

<sup>c</sup> Data from all three of the available studies of hair mercury levels indicate that the top 5% of the population has exposures to mercury that exceed the RfD (see page 324 of NRC report). (Note: data from the Continuing Surveys of Food Intake by Individuals, 1989/1990 indicate that the top 5% of the fish consuming population consume at least 100 g of fish/day.) In addition, both the WHO/IPCS have identified women of childbearing age who consume at least 100 g of fish/day as requiring special attention with respect to the hazards of mercury and the EPA has estimated that, based on food consumption surveys, that the RfD is exceeded at approximately the 93rd percentile of all women (EPA 1997 Report to Congress, Volume VII, pages 6-22 and 6-29).

<sup>d</sup> From National Center for Health Statistics, National Vital Statistics Report, Vol. 48, No. 3, March 2000