CALUX™ AND GC/MS ANALYSIS OF TEQ CONTAMINATION FOR RISK ASSESSMENT OF EXPOSURE TO DIOXINS IN ICE CREAM

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Introduction:

Polychlorinated dioxins and furans, hereinafter referred to as "dioxin" or "dioxins," are ubiquitous compounds that have generated much controversy because of their great toxicity in laboratory animal experiments. Dioxin has been called "the most deadly compound ever assembled by man." Ben & Jerry's Homemade Holdings, Inc. ("Ben & Jerry's) states in promotional literature that "The only safe level of dioxin exposure is no exposure at all." A sample of Ben & Jerry's "World's Best Vanilla" ice cream was analyzed by the CALUXTM bioassay and by high resolution gas chromatography/high resolution mass spectrometry (HRGC/HRMS). The two measurements were in good agreement. Based on those measurements, a single serving of Ben & Jerry's ice cream contains about 190 times the "virtually safe [daily] dose" of dioxin, as calculated by the U.S. Environmental Protection Agency.

Materials and Methods:

A sample of Ben & Jerry's "World's Best Vanilla"® ice cream was purchased in Montgomery County, Maryland, and delivered to Xenobiotic Detection Systems for analysis.

CALUXTM Assay: Xenobiotic Detection Systems, Inc. (XDS), has a patented genetically engineered cell line which contains the firefly luciferase gene under trans-activational control of the aryl hydrocarbon receptor.³ The cell line can be used for the detection and relative quantification of PCDDs, PCDFs, and coplanar PCBs when used with our patent pending sample processing procedure.⁴ The assay using this cell line is called the Chemical-Activated Luciferase expression, or CALUXTM assay. The sample was analyzed and compared to a XDS method blank. The sample was significantly more active in the CALUXTM bioassay than the blank and the quantification of TEQ activity relative to 2,3,7,8-tetrachlorodibenzo-p-dioxin was used to determine TEQ activity in the sample.

HRGC/HRMS Analysis: A sample of Ben & Jerry's "World's Best Vanilla" ice cream was delivered to Paradigm Laboratories, Wilmington, NC. The sample was analyzed by EPA method 8290 for congener specific determination of chlorinated dibenzo-p-dioxins and furans. TEQ was calculated by multiplying the congener specific concentration of the detection limit by the WHO TEF value for each congener.

Results and Discussion:

The concentrations of dioxin in the ice cream sample as determined by HRGC/HRMS and the CALUXTM assay were similar. Table 1 shows the concentration of dioxin TEQ in the ice cream and the concentration on a lipid adjusted basis. Based on either measurement, the calculated amount of dioxin consumed in a single serving of the ice cream is about 80 picograms (pg, one trillionth of a gram).

Table 1: Concentrations of Dioxin in Sampled Ice Cream and Exposure to Dioxin from One Serving

Sample	Dioxin TEQ ppt ¹	Dioxin TEQ ppt ²	Weight ice cream single serving (grams)	Weight of dioxin single serving (picograms) ⁴
Ice Cream	0.898	0.79 ± 0.38	107 ³	84
Ice Cream Lipids		5.1 ± 1.3	16 ³	82

- 1 TEQ determined from HRGC/HRMS
- 2 TEQ determined by CALUXTM assay
- 3 From information on the ice cream package.
- 4 From CALUXTM determination

Dioxins were present in Ben & Jerry's "World's Best Vanilla"® ice cream as determined by HRGC/HRMS and the CALUXTM assays. This may be of concern because, as Ben & Jerry's states, "The only safe level of dioxin exposure is no exposure at all." The U.S. Environmental Protection Agency (EPA) agrees with that statement, and holds the view that any exposure, no matter how small, increases the risk of cancer.

The EPA has calculated a "virtually safe dose" (VSD) for dioxin, which is the exposure to dioxin associated with one additional case of cancer per million people exposed on a daily basis over their lifetimes. The VSD is generally regarded as an acceptably low exposure. For dioxin, the VSD is 0.006 pg TEQ/kilogram body weight/day (pg/kg bw/d). The amount of dioxin in a serving of the tested ice cream is about 80 pg TEQ/serving (see Table 1) and exceeds the VSD.

Assuming the average consumer weighs 70 kilograms (kg), the dose of dioxin from one serving of the tested ice cream is 1.14 pg TEQ/kg bw/day.⁸ This dose rate is 190 times greater than the EPA's VSD, meaning that 190 dioxin-caused cancers may be expected among every million people who consume that amount of ice cream on a daily basis.

We calculated the number of dioxin-caused cancers that might occur in people who consume Ben & Jerry's ice cream. We assumed that our measurement of dioxin is correct and that it is representative of all Ben & Jerry's ice cream manufactured and that all the ice cream manufactured is consumed. We assumed, consistent with Ben & Jerry's promotional literature and EPA policy, that dioxin causes cancer and that there is no safe level of exposure to dioxin.

According to the company, Ben & Jerry's manufactures 13 million gallons of ice cream per year. This equals 416 million servings of Ben & Jerry's ice cream per year. 10

If consumers eat one serving of Ben & Jerry's ice cream per day, the number of daily consumers is 1.1 million¹¹ and an additional 209 cases of cancer may be expected among those people over a 70-year lifetime.¹²

Because of the assumption that there is no safe level of dioxin consumption, reducing the amount of ice cream consumed per person does not decrease the number of estimated cancer cases on a population basis. It does, however, reduce the risk for individual consumers. See Table 2.

Table 2. Estimated Cancer Risks from Dioxin in Ben & Jerry's Ice Cream

Frequency of consumption of ice cream servings	Number of consumers ^a	Times in excess of EPA VSD for dioxin ^b	Number of cancer cases	Lifetime risk of cancer per consumer
Daily	1.1 million	190	209	1.9 x 10 ⁻⁴
Every other day	2.2 million	95	209	0.95 x 10 ⁻⁴
Every 4 th day	4.4 million	47.5	209	0.47 x 10 ⁻⁴
Every 10 th day	11 million	19	209	0.19 x 10 ⁻⁴
Every 100 th day	111 million	1.9	209	0.02 x 10 ⁻⁴

a - The number of consumers required to eat the 1.1 million daily servings goers up as the frequency of consumption goes down.

This study has the major limitation that only one sample of ice cream was tested. This sample may or may not be representative of all Ben & Jerry's ice cream. There is measurement error associated with our sample. Concentrations of dioxin in Ben & Jerry's ice cream may be greater or less than measured in our sample. Variation in the levels of dioxin would either raise or lower the risk estimates presented here. However, our measurement of approximately 5 ppt TEQ in lipids is consistent with previous findings. ¹³

More important for the interpretation of our results, we do not believe that credible scientific evidence leads to the conclusion that dioxin causes cancer in humans. Studies of populations exposed to high levels of dioxin as a result of the industrial explosion at Seveso, Italy¹⁴ and participation in the U.S. Air Force Ranch Hand project during the Vietnam War (spraying Agent Orange)¹⁵ do not support the hypothesis that dioxin is a human carcinogen.

Ben & Jerry's states in promotional literature that "The only safe level of dioxin exposure is no exposure at all." Our data indicate that Ben & Jerry's "World's Best Vanilla"® ice cream contains dioxins. Assuming the measurement is correct and that it is representative of Ben & Jerry's ice cream, and based on U.S. Government information about the potential health effects of dioxin, Ben & Jerry's ice cream may cause about two hundred of cases of cancer among its consumers.

b - The exposure of someone who eats ice cream every other day is one-half the exposure of the daily consumer and so forth. Therefore, her dose, expressed as a multiple of the VSD, decreases by one-half also.

Endnotes:

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United Press International. 1983. "Dioxin — A Ticking Time Bomb 170,000 Times As Deadly As Cyanide," March 11, 1983.

Ben & Jerry's Holdings, Inc. 1999. "Our Thought On Dioxin" (brochure).

Denison, M., Brouwer. A. and Clark, G. U.S. patent #5,854,010.

⁴ Chu, M. and Clark, G. Patent application submitted.

⁵ US EPA Method 8290, September 1994.

Van den Berg, M., et al. (1998) Env. Health Perspectives. 106, 775.

⁷ U.S. EPA. 1985. Health Assessment Document for Chlorodibenzo-p-dioxins (EPA600/8-84-014A).

⁸ 80 pg TEQ x person/70 kg bw.

⁹ Correspondence from Ben & Jerry's.

¹³ million gallons year x 8 pints per gallon x 4 servings per pint.

⁴¹⁶ million servings per year divided by 365 days per year.

Daily consumers (1.1 million) x 190 cancer/million exposed people.

Schecter, A et al. 1994. "Congener-specific levels of dioxins and dibenzofurans in U.S. food and estimated daily dioxin toxic equivalent intake." *Environmental Health Perspectives* 102:962-966.

Bertazzi, PA et al. 1997. "Dioxin exposure and cancer risk. A 15-year mortality study after the Seveso accident." *Epidemiology*, 8:646-652.

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