



Attachment B

Information Regarding Release of Raw Data

August 2012
Toxics Cleanup Program
Washington State Department of Ecology
Olympia, Washington

Contents

Letter from Columbia River Inter-Tribal Fish Commission

Letter from University of Washington School of Public Health



COLUMBIA RIVER INTER-TRIBAL FISH COMMISSION

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March 19, 2012

Ted Sturdevant
Director
Washington Department of Ecology
P.O. Box 47600
Lacey, WA 98504

Dear Mr. Sturdevant:

I understand that you have received requests to make the raw data contained in the Columbia River Inter-Tribal Commission's (CRITFC) fish consumption survey available for public scrutiny and review because of a perceived lack of technical quality and external peer review. This perception is unfounded and I find their requests disturbing. The study's design, implementation, and analysis were described in "A Fish Consumption Survey of the Umatilla, Nez Perce, Yakama, and Warm Springs Tribes of the Columbia River Basin, Technical Report 94-3, Portland, Oregon, 1994" were rigorously developed, closely examined, and thoroughly vetted before publication. I would like to highlight the following points that support the scientific defensibility of the survey.

- A technical panel was established to assist in the design and implementation of the survey. The panel consisted of 17 members and included technical staff from CRITFC, as well as toxicologists, epidemiologists, health scientists, and environmental scientists from the Indian Health Service (IHS), the Centers for Disease Control (CDC), Washington and Oregon state health departments, EPA Region 10, and EPA Headquarters.
- Interviewers were trained by the CDC and were instructed in surveying procedure and techniques during a three-day session. The questionnaire was reviewed question-by-question with all interviewers and training included practice interviews in the presence of an instructor. Models were used to help reflect types and amounts of fish consumed.
- A total of 513 tribal members at least 18 years old were directly surveyed. These respondents provided information for 204 children age 5 or younger (one child per household). Respondents were selected by the CDC using a systematic probability sampling method, randomly selected from Indian Health Service client lists of tribal members. Data were collected for the survey using stratified

systematic sampling with each of the four tribes considered an independent stratum.

- Survey data were transferred from questionnaire format to a computer format and were reviewed for missing answers or mistakes in data entry. Survey data were analyzed by CDC's statistical database package used for analysis of epidemiological data. A second complete audit of the database was conducted by a private consulting firm and involved a question-by-question review of each survey. Appropriate statistical tests were used to evaluate the data. The Shapiro-Wilk test was used because the sample size was less than 2,000 and indicated that the data set was not a purely random distribution, but rather reflected meaningful trends. Outliers whose data points seemed unreasonably high due to discontinuity in distribution were ignored in all calculations. It should be noted that these outliers probably reflected "more traditional" consumption patterns, but were not used in the analyses.
- The study design, implementation strategy, and analyses were submitted to an independent peer review panel. The peer review panel consisted of the following members: Dr. Patrick West, PhD, University of Michigan; Dr. Douglas Robeson, Ph.D., Ottawa, Ontario; Dr. Clayton Stunkard, Silver Spring, MD; Dr. H. Joseph Sekerke, Jr., State of Florida Dept. of Health and Rehab. Services; Dr. Mary Yoshiko Hama, Ph.D., US Dept. of Agriculture, Food Consumption Research Branch; Dr. Kenneth Rudo, Ph.D., State of North Carolina, Dept. of Environmental Health, Division of Epidemiology; Dr. Yasmin Cypel, Ph.D., U.S. Dept. of Agriculture, Food Consumption Research Branch; Dr. Rolf Hartung, Ph.D., Dept. of Environmental and Industrial Health, University of Michigan; and Dr. Dale Hattis, Ph.D. Clark University.
- Additional credibility of the CRITFC survey design is further supported by its use as a template for other Pacific Northwest dietary surveys with refinements specific for the population being surveyed. In addition, the CRITFC survey has been referred to in national guidance for policies and procedures for evaluating exposures (EPA's Exposure Factors Handbook – 2009 Update and 2011 Edition).

Not only is the data in the CRITFC report scientifically defensible, it reflects reasonable fish consumption habits and mirrors national survey data for fish-consuming Americans. The data presented in the CRITFC report indicates that the average Columbia River tribal adult consumes 63 grams per day of fish. This information can be compared to the US national average fish consumption rate of fish consuming adults reported in EPA's 2002 "Estimated Per Capita Fish Consumption in the United States." This study reports dietary intake from two days of recall provided by a nationally representative sample of 4,391 fish-consuming individuals over a four-year period. The national average fish consumption rate for fish by adults (age >15) is 127 grams per day (2002 EPA Report, Section 5.2.1.1 Table 3, page 5-42). The 2002 national average is twice as high as that for tribal members surveyed by CRITFC in 1991-1992.

The lower than national average fish consumption rate reported in the CRITFC survey may be explained in part by the fact that more than 61% of the survey respondents reported that their fish consumption was suppressed by poor fish harvests during the early 1990's. Fish counts at Lower Granite Dam, reported by the US Army Corps of Engineers (USACE) confirm that spring and summer chinook availability in the Columbia Basin at the time of the CRITFC survey (1991-1992) was close to 80% lower, steelhead was nearly 50% lower, and fall chinook was 94% lower than at the time of the 2002 EPA national survey. Fish availability is similar today compared to 2002 and continues to improve for fall chinook. This data is presented in the following table which is available at the USACE web site (<http://www.nwp.usace.army.mil/environment/fishdata.asp>). We expect that tribal fish consumption would have improved since the time of the CRITFC survey as well and is now at the same level or higher than the national average.

Year	Lower Granite Dam Counts		
	Total Spring and Summer Chinook	Annual Steelhead Counts	Fall Chinook
1991	10,432	100,381	630
1992	24,405	121,459	855
2002	97,184	218,718	12,351
2010	122,981	203,301	41,815

It is worthwhile to note that the fish consumption rate adopted by Oregon of 175 grams per day is not an unreasonable number or a culturally biased exaggeration. The value used by Oregon is based on a rate that is protective of the 95th percentile of the CRITFC survey respondents or 176 grams per day. By comparison, the 95th percentile fish consumption rate for the national population of fish consumers in the 2002 EPA report is 334 grams per day (Section 5.2.1.1, Table 4, page 5-43). 175 grams per day is equivalent to about 144 pounds of fish per year. According to a World Resources Institute (www.wri.org) survey, in 2004 Americans consumed an average amount of 275 pounds of meat per year. The Oregon fish consumption rate is reflective of the habits of a fish-consuming, Pacific Northwest lifestyle.

Finally, we will not violate the confidentiality agreements made in 1991-92 with tribal members that participated in the survey. In addition to responses about food consumption, tribal members were asked questions about personal and family habits such as breastfeeding, ceremonial attendance, and subsistence lifestyles. Survey participants understood that this information would be private and not debated in a public forum. Fish consumption by tribal members reported in the CRITFC survey is technically defensible, was subject to external peer review by independent scientists, is within range of the values identified in EPA's 2002 national average of fish consumers, is lower than the average meat consumption of average Americans, and is a realistic value. The need to question the validity or quality of the survey is unwarranted and a request to have access to the personal information of survey respondents is unnecessary.

It has been 20 years since CRITFC conducted this fish consumption survey and proved that tribal members and others that consume fish have not been adequately protected by Washington State's water quality criteria. Rather than debate the fact that Washingtonians eat fish, it is time for the State to take action and reduce exposure to waterborne toxic contaminants and to protect the health of all Washington residents.

Thank you for your consideration of this important issue. If you have any further questions, you may contact Dianne Barton, PhD or me at (503) 238-0667.

Sincerely,

A handwritten signature in blue ink that reads "Babtist Paul Lumley". The signature is stylized and cursive.

Babtist Paul Lumley
Executive Director

Cc: Dennis McLerran, Regional Administrator, EPA



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March 20, 2012

Craig McCormack
Toxics Cleanup Program
Department of Ecology
Lacey, WA
(sent via email: cmcc461@ECY.WA.GOV)

Subject: Release of research data

Dear Craig,

I am writing in response to the question you posed, “Based on your professional academic experience as an environmental epidemiologist and your technical peer reviewed publication record, can you please explain to me if you are required to release raw data into the public domain from surveys or the research you have conducted prior to the publication of the survey or research information in peer reviewed technical journals?”

In general, research data are only released or shared in special and controlled circumstances.

You asked specifically about peer review and publication. Peer review of a journal manuscript or technical report is almost always conducted solely on the basis of the submitted manuscript, author responses to questions or comments posed by the editor or reviewers, and author revisions of the manuscript. I am not aware of any journal or other formal technical review process where authors are expected to provide their raw data as part of the peer review. That would be extremely unconventional, and I anticipate that most if not all researchers would choose a different publication venue if that was a condition of publication.

You mentioned in a conversation that this question grows out of a situation involving a technical report for a research study. I will mention that the peer review process for technical reports is, in spite of common perceptions, often much *more* rigorous than for journal manuscripts. It is common for a journal manuscript to be reviewed by only 2 or maybe 3 peer reviewers, and sometimes just 1 reviewer. In contrast, technical reports commonly go through internal review within the research institution, and then go through external peer review by 2 or 3 and often more experts at unaffiliated institutions. If a published report has undergone a review of such rigor, it would be very reasonable to consider it as credible as a published journal article.

There are definitely some circumstances in which a researcher might share or release research data. These usually involve either a collaborative research arrangement between the original researcher and a new researcher, or a formal structured data sharing plan. Collaboration or a plan is invariably necessary to ensure that data are interpreted and used correctly. Otherwise, it may not be obvious to a naïve user what is represented by individual variables or their coded values in an electronic data set, or that some variables were ultimately determined to be nuanced or unreliable (for example, a survey question might have been interpreted differently by different

participants). It also must be ensured that the rights and privacy of study participants are not violated.

I will mention that federally funded research requires a data sharing plan for relatively large studies (>\$500,000 per year), unless there are concerns about risk to participants' privacy because the sample size is small or the data are particularly sensitive. This does not mean that data must be released unconditionally. It is common to utilize a restricted access plan, where potential users must submit a proposal for review by a coordinating center.

I hope I have addressed all aspects of your question. If you have additional questions, please do not hesitate to contact me again.

Sincerely,

A handwritten signature in blue ink that reads "William Daniell". The signature is written in a cursive style with a circled "D" at the end.

William Daniell, MD MPH
Associate Professor

cc: Martha Hankins
Toxics Cleanup Program
Department of Ecology

Rob Duff
Program Manager
Environmental Assessment Program
Department of Ecology