



March 11, 2011

Kelly Richardson
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Subject: Expert Opinion Letter Regarding the Draft Technical Report for Tentative
Cleanup and Abatement Order No. R9-2011-0001

Dear Mr. Richardson:

I have prepared the attached report regarding the potential human health risks associated with consumption of fish and shellfish in and around the National Steel and Shipbuilding Company (NASSCO) shipyard in the San Diego Bay, California. It is my understanding that I have been retained by NASSCO counsel to offer my opinions about the risk assessment prepared by the California Regional Water Quality Control Board (RWQCB) as a part of their Revised Tentative Cleanup and Abatement Order No. R9-2011-0001 (dated September, 2010). In addition, I have been asked to prepare alternative risk estimates (using more refined and appropriate assumptions) in a manner consistent with regulatory risk assessment guidance and the most recent published scientific literature. Similar to the RWQCB risk assessment, my analysis addresses theoretical risks for anglers due to consumption of fish caught from within the NASSCO leasehold. In this report, I provide estimates of cancer and non-cancer risk associated with exposure to arsenic, PCBs, mercury, cadmium, and copper (these chemicals were identified in the RWQCB risk assessment as posing either a cancer or non-cancer risk to anglers at the Shipyard Sediment Site, which includes the NASSCO shipyard) based on established risk assessment practices.

My opinions are based on my professional qualifications and experience. In this report, I provide a brief overview of my background and areas of expertise relating to this matter, including a summary of my knowledge of industrial hygiene, toxicology, exposure, and risk assessment.

Respectfully,

A handwritten signature in black ink that reads "Brent L. Finley".

Brent L. Finley, Ph.D., DABT
Principal Health Scientist
Attachment



**Expert Report of
Brent L. Finley, Ph.D., DABT**

*Prepared in Regards to the California Regional Water Quality Control Board's Draft
Technical Report for Tentative Cleanup and Abatement Order No. R9-2011-0001
(San Diego Bay)*

Prepared for

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March 11, 2011

I. EXPERIENCE

I am a board-certified toxicologist with over 20 years of experience conducting and managing studies involving chemical exposure and human health risk assessment. I have a bachelor's degree in Biological Sciences from Cornell University and a Ph.D. in Pharmacology/Toxicology from Washington State University. I am a principal and vice president at ChemRisk[®], a consulting firm providing state-of-the-art toxicology, industrial hygiene, epidemiology, and risk assessment services to organizations that face public health, occupational health, and environmental challenges. Over the last 15 years, I have authored over 500 health risk assessments related to the presence of chemicals in consumer products, foods, the environment, the workplace, households, and other settings. I have published over 60 peer-reviewed articles related to dioxins, polychlorinated biphenyls (PCBs), chromium, chlorinated solvents, asbestos, and latex allergens, among others. I have taught risk assessment courses at universities, have given numerous invited lectures, and have served on several risk assessment expert panels. I have been deposed and testified in state and federal court on matters related to chemical exposure and potential adverse effects in humans.

Over the course of my career, I have conducted numerous human health risk assessments for settings that are similar to the NASSCO leasehold, including a Superfund site involving arsenic and PCB-contaminated sediments and fish in the Passaic River in New Jersey. In total, I have published over 25 papers regarding the proper use of exposure and risk assessment techniques, including publications that specifically address the potential for chemical exposure via fish consumption.

My curriculum vitae, which presents my background and training, is included as Appendix B.

II. MATERIALS REVIEWED IN FORMULATING OPINIONS

My opinions are provided in Sections IV and V of this report. My opinions are based on my professional qualifications, work experiences, and knowledge of industrial hygiene, toxicology, risk assessment, and related fields. My opinions also are based on information that is related to this case. In the process of preparing this report, I or my colleagues have reviewed and relied upon the following documents: (1) First Amended Order of Proceedings, California Regional Water Quality Control Board San Diego Region (Dated January 30, 2006), (2) Comments Regarding Pre-Hearing Conference Issues (Dated September 20, 2005), (3) California Regional Water Quality Control Board San Diego Region RE: Assessment and Remediation of Contaminated Sediment in San Diego Bay at NASSCO and Southwest Marine Shipyards (Dated June 1, 2001), (4) Tentative Cleanup and Abatement Order No R9-2005-0126 for...Contaminated Marine Sediment in San Diego Bay etc (Dated April 29, 2005), (5) NASSCO and Southwest Marine Detailed Sediment Investigation Vol. I, prepared by Exponent (Dated October 2003), (6) NASSCO and Southwest Marine Detailed Sediment Investigation Vol. II – Appendices A-E, prepared by Exponent (Dated October 2003), (7) NASSCO and Southwest Marine Detailed Sediment Investigation Vol. III- Appendices F-P, prepared by Exponent (Dated October 2003), (8) Review of the Exponent NASSCO and Southwest Marine Detailed Sediment Investigation (Dated April 29, 2004), (9) Exponent documentation of tissue sample results (not dated), (10) Responses to OEHHA Comments on the NASSCO and Southwest Marine Detailed

Sediment Investigation Report (Dated June 7, 2004), (11) Draft Technical Report for Tentative Cleanup and Abatement Order No. R9-2005-0126 (Available online August, 2007 and April 4, 2008), (12) Tentative California Regional Water Quality Control Board San Diego Region Revised Tentative Cleanup and Abatement Order No. R9-2005-0126 (Available online August, 2007 and April 4, 2008), (13) Report titled "Survey of Fishers on Piers in San Diego Bay" by the Environmental Health Coalition (Dated March 2005), (14) Letter from EHC to the San Diego Regional Board regarding "How to Achieve Environmental Justice Using a Precautionary Approach in Environmental Decisions: Recommendations for Sediment Quality Decision in San Diego Bay (Dated June 15, 2005), (15) San Diego Bay Health Risk Study (prepared for the Port of San Diego by the San Diego Department of Health Services, dated June 12, 1990), (16) The Unified Port of San Diego's Port Master Plan (dated 2009), (17) various documents related to usage plans for the Port of San Diego, (18) Draft Technical Report for Tentative Cleanup and Abatement Order No. R9-2010-0002. Prepared by the California Regional Water Quality Control Board, San Diego Region, Volumes I and II (Dated December 22, 2009), (19) Tentative Cleanup and Abatement Order No. R9-2010-0002. Prepared by the California Regional Water Quality Control Board, San Diego Region (Dated December 22, 2009), (20) Tentative Cleanup and Abatement Order No. R9-2011-0001 (dated September 15, 2010), (21) Draft Technical Report for Tentative Cleanup and Abatement – Volumes I, II, and III (dated September 15, 2010), (22) various RWQCB administrative record documents and index (23) approximately 650 hours of security footage from the NASSCO shipyard, (24) various documents related to NASSCO security measures, (25) published creel angler surveys and fish consumption studies, (26) published papers and textbooks on the toxicology of the contaminants of concern available in the open literature, (27) U.S. Environmental Protection Agency (EPA) risk assessment and exposure assessment guidance, and (28) facts or data reasonably relied upon by persons in my field. Specific references cited in my opinions are listed at the end of this report. My opinions are expressed to a reasonable degree of scientific certainty.

These opinions are based on information available to me on the date of this report. I have provided a list of documents that were reviewed in forming my opinions. This report may be supplemented if new information becomes available.

III. BACKGROUND

The NASSCO shipyard is located on the eastern shore of San Diego Bay, approximately halfway between the mouth of the bay and its inner end. It is one of several shipyards in the area and provides ship construction and repair services to both commercial customers and the Navy. The site has been used for industrial purposes for most of the 20th century. Based on port plans and other such documents specific to the San Diego Bay, it does not appear as though this leasehold will be used as a recreational area in the foreseeable future (City of San Diego 2006; Unified Port of San Diego 2009).

The site is characterized by a lack of public access. The physical layout of the site is comprised of approximately 126 acres of tideland property, including about 80 acres of upland area and 46 acres of water area. The shipyard contains two building ways, eight ship berths, a graving dock, and a floating dry dock. A sheet pile bulkhead and a seawall form the boundary between land

and sea for most of the facility shoreline. This is, in part, due to Navy requirements that prohibit non-essential vessels from approaching Navy ships. Accordingly, a security boom is in place that prevents unauthorized vessels from approaching closer than 300 ft from the shipyard. From land, the general public is also prohibited from entering the shipyard leasehold due to the presence of armed security guards and other barriers, such as buildings or eight-foot fences with razor wire.

Security measures are enforced in several ways, including 1) the use of video cameras to monitor all entrances/exits, perimeter barriers and the water line; 2) requirement of identification for anyone entering or exiting the premises (any visitors must be pre-approved); 3) regular security rounds by security personnel (generally between four and 20 dedicated Security Officers are on site at any given time and security rounds specifically include all perimeters and areas of waterfront access); and 4) alarm systems (NASSCO 2006).

Further, entry onto the facility requires showing an identification card to an electronic scanner or security cards, and friend or family visits are generally limited to specific, pre-approved days (such as for a launch or naming day). Approved guests are escorted at all times (NASSCO 2004). Entrance and exit gates are either guarded by security, locked with razor wire during non-operational hours, or contain turn stalls, which are immobile until identification is detected. Response plans for “security incident procedures,” which include the presence of unauthorized personnel anywhere on the facility (including the shoreline) or any unauthorized vessels moored along the waterfront property (which could include fishing boats), include questioning the individual in detail and notifying local police.

In 2001, the shipyard conducted a sediment investigation in response to Resolutions No. 2001-02 and 2001-03, adopted by the RWQCB, on February 21, 2001. The RWQCB directed the investigation, which was intended to determine areas for possible sediment remediation. Fieldwork was conducted by Exponent, a consulting company, in two phases, in 2001 and 2002. Chemical analyses were conducted on sediment (surface and subsurface), pore water, and tissues of indigenous organisms. Other evaluations included mineralogical microprobe analyses; sediment toxicity tests measuring amphipod survival, echinoderm fertilization, and bivalve larvae development; sediment profile images; benthic macroinvertebrate community analyses; chemical bioaccumulation tests; histopathological examinations of fish; and analyses of fish bile for PAH breakdown products. The extensive data from these investigations were used to evaluate the horizontal and vertical distribution of shipyard associated chemicals, to evaluate adverse impacts on benthic macroinvertebrates and fish, and to conduct risk assessments for aquatic-dependent wildlife and human health.

Fish and shellfish tissue samples were collected at locations inside the leasehold, in the waterways directly outside the leasehold, as well as reference (or “background”) locations. Spiny lobsters (*Panulirus interruptus*) were collected in crab traps. Chemical analyses of lobster were performed on both edible tissue (all soft tissue, including the hepatopancreas) and on the entire organism including the shell. Soft tissue was removed in the laboratory prior to analysis. The fish species collected were northern anchovy (*Engraulis mordax*), Pacific sardine (*Sardinops sagax*), and spotted sand bass (*Paralabrax maculatofasciatus*). Species included in the human health

risk assessment portion of the RWQCB investigation were limited to the spiny lobster and spotted sand bass.

IV. OVERVIEW OF OPINIONS

I have briefly summarized the substance of my opinions below. More detail is provided in Section V and Appendix A.

- The RWQCB refers to their analysis as a two-tiered, comprehensive risk assessment when in fact they conducted two separate worst-case screening analyses, one using data collected from clams, the other using fish/shellfish data. This is inconsistent with standard risk assessment practice.
- The exposure assumptions used in the RWQCB's Tier II assessment were overly conservative and unrealistic.
 - The RWQCB based their risk assessment on maximum tissue concentrations for fish and shellfish, which is a "worst case" approach that does not accurately portray the variability of chemical concentrations in the fish and shellfish populations.
 - The RWQCB assumed that subsistence anglers would *always* consume the *entire* fish or shellfish (guts and all), which is completely unfounded and only serves to overestimate risk. It also runs counter to the information collected in a detailed study of anglers *in the San Diego Bay* (County of San Diego 1990).
 - The RWQCB employed fish consumption rates from the anglers in the Santa Monica Bay. Considering the lack of access and industrial nature of the NASSCO shipyard, the use of fish consumption rates from the Santa Monica Bay, a highly accessible recreational area, is inappropriate and inconsistent with the practice of risk assessment in general and regulatory risk assessment guidance in particular.
 - Based on my evaluation of the security measures in place at NASSCO, it would be impossible for an angler to access the shipyard and catch fish on a consistent basis, much less *every single day for 30 years* (as was assumed by the RWQCB).
- The RWQCB failed to acknowledge that the fish/shellfish contaminant levels measured in the NASSCO leasehold are statistically indistinguishable from those measured outside the leasehold (including the background reference locations specifically selected by the RWQCB), which suggests that any discharges by NASSCO do *not* appear to have influenced fish/shellfish tissue concentrations.
- Based on my risk assessment, which is conservative and consistent with regulatory guidance, cancer and non-cancer risks associated with consumption of fish and shellfish caught in the NASSCO leasehold are well below levels of regulatory concern.

V. OPINIONS

The basis of my opinions is as follows:

- 1. The RWQCB has apparently misinterpreted the terms “screening” and “comprehensive” risk assessment as they are defined in the EPA risk assessment guidance documents that the RWQCB purports to follow. For example, the Tier II “comprehensive” risk assessment is in fact a worst-case screening analysis. Little attempt was made to develop accurate or refined estimates of potential human health risk via iterative analyses and therefore the use of the RWQCB “comprehensive” assessment for decision-making purposes is inconsistent with regulatory risk assessment guidance.**

Risk assessment is the process used to estimate the likelihood of an adverse effect of a chemical or physical agent under a specific set of conditions. This process has been well-established for over two decades (NRC 1983). Numerous regulatory guidance documents have been published that describe general approaches to preparing pertinent assessments using the most appropriate available data. Risk assessment can be divided into four major steps: hazard identification, dose-response assessment, exposure assessment, and risk characterization. These elements are present regardless of whether one is conducting a screening assessment or a comprehensive risk assessment. The purpose of risk assessment is to provide objective and quantitative information to risk managers (e.g., policymakers, regulators) so that the best possible decisions can be made.

Numerous regulatory risk assessment guidance documents, particularly those relied upon by the RWQCB, describe an iterative, step-wise risk assessment process (USEPA 1989b). The purpose of the first step, a screening analysis, is to initially determine whether significant theoretical risks could exist under conditions that involve default, non-site-specific, and highly conservative exposure assumptions. If the results indicate lack of a significant risk under such conditions, then no further examination is required. If the screening analysis indicates that some or all of the contaminants of concern may pose a health risk, then a more refined (“comprehensive”) analysis is conducted using the initial results of the screening analysis but more realistic and plausible (yet still conservative) site-specific exposure assumptions. Additional iterations may be developed if new information (e.g., sampling data) becomes available. Risk estimates generated from the final analyses are then used for remedial decision-making purposes.

The concept of a screening analysis followed by a refined analysis (which includes “more probable exposures” and “central estimates with lower and upper bounds,” among other things) is specifically described in several EPA risk assessment guidance documents:

“...it is important to remember that if a screening level approach suggests a potential health concern, *the estimates of exposure should be modified to reflect more probable exposure conditions*” ((USEPA 1989b); p. 6-25). [emphasis added]

“Screening-level assessments may more readily use default parameters, even worst-case assumptions, *that would not be appropriate in a full-scale assessment...significant risk*

management decisions will often benefit from a more comprehensive assessment...such assessments should provide central estimates of potential risks in conjunction with lower and upper bounds (e.g., confidence limits) and a clear statement of the uncertainty associated with these estimates” ((USEPA 2005); p. 1-9 – 1-10). [emphasis added]

I note that the USEPA 1989 Risk Assessment Guidance for Superfund (USEPA 1989b), quoted above, is the primary guidance document cited in the RWQCB assessment.

Overall, I find that comparing surrogate clam data to the RWQCB’s criteria (in terms of a human health risk screening analysis) is questionable for many reasons: 1) they are based on laboratory-generated bioaccumulation data that may have no relevance to actual environmental conditions, 2) no evidence was presented to indicate that these clams are collected and consumed by anglers in the NASSCO leasehold, 3) the original “clam criteria” were developed for freshwater bodies, and 4) the RWQCB applied subsistence fish consumption rates to clam tissues.

In their technical report, the RWQCB presented what was termed a “Tier I screening level risk assessment” which was intended to determine any potential risk to human health and to determine if a more comprehensive risk assessment was necessary (CRWQCB 2010a). In the Tier I assessment, levels of contaminants that bioaccumulated in clam tissues from San Diego Bay sediments were compared to ad-hoc criteria developed by the RWQCB. Clam tissue data were used as a surrogate for fish and shellfish that would actually be consumed by anglers. Further, these tests were conducted in a laboratory setting and do not even represent tissue concentrations from clams in the bay.

More importantly, there was no reason to conduct this analysis because fish tissue concentrations from the NASSCO leasehold were readily available (Exponent 2003). The species of clam used in the assay, *Macoma nasuta*, is relatively small (3-7 cm in length, with only 1-6 g of potentially edible tissue). Thus using the high subsistence fish consumption rate of 161 g/day employed by the RWQCB, one would have to consume between 25-100 clams from the leasehold every day to achieve the risk estimates presented in the Tier I analysis. The RWQCB offers no insight as to why they did not simply use the available fish tissue data in conjunction with conservative fish consumption rates to conduct a standard and customary screening analysis.

Even more surprising is the fact that the results from this analysis (e.g., identification of chemicals of interest) were ignored in the subsequent “Tier II” assessment. In my view, the RWQCB should have conducted a screening analysis in Tier I wherein the available site-specific edible fish tissue data could be used in conjunction with default, conservative exposure assumptions. Indeed, this is precisely what the RWQCB offers as a refined “Tier II analysis.”

As noted above, the iterative risk assessment process is intended to ultimately yield risk estimates that are conservative yet still plausible (often referred to as a “reasonable maximal exposure”) (USEPA 1989b); p. 6-4). This can be done by conducting a deterministic risk assessment (where point estimates are used in risk calculations) or by performing a probabilistic risk assessment (which is based on the statistical distributions associated with each exposure assumption). Either way, for the purposes of decision-making, a range of plausible risk estimates should be presented via a series of alternative exposure assumptions or via a

probabilistic analysis with a reasonable maximal “point estimate” identified on the distribution of risk estimates.

Probabilistic techniques (also referred to as “Monte Carlo analysis”) involve repeated random sampling from distributions of values for each parameter included in an exposure or dose calculation. These values, in turn, are used to derive an estimate of the distribution of exposures or doses in the population ((EPA 1992); p. 112). Additionally, Monte Carlo analysis also allows one to characterize, quantitatively, the uncertainty and variability associated with exposure or risk estimates ((USEPA 1997c); p. 3).

Numerous risk assessment guidance documents and scientific publications describe the benefits of the probabilistic methodologies and they are now considered standard and customary and have been for some time (Finley and Paustenbach 1994; Finley, Proctor et al. 1994; USEPA 1997c). Indeed, default distributions for most exposure assumptions have been available in the published literature for over 10 years. The risk estimates should also be accompanied by a quantitative uncertainty or sensitivity analysis.

The RWQCB did none of the above. They discarded the Tier I analysis altogether and “went back to square one” to prepare the Tier II analysis, wherein they conducted the most simplistic and conservative deterministic assessment possible with the available data. As a result, the risk estimates are completely implausible. For example, the “comprehensive Tier II analysis” is actually driven by the assumptions that a person will somehow visit the NASSCO leasehold (despite the lack of access from both land and water) and consume fish/shellfish containing the maximum measured concentrations every day for 30 years. This clearly does not fit the definition of a reasonable maximal exposure and is in fact a worst-case screening analysis.

Interestingly, I note that a two-tiered risk assessment was performed by the San Diego County Department of Health Services (SDCDHS) in the 1990s. Unlike the RWQCB’s “Tier I” analysis, the Phase I assessment in the San Diego Bay Health Risk Study (hereafter referred to as the “Health Risk Study”) is much more consistent with regulatory guidance, as is their more refined Phase II risk assessment. As will be described in more detail later, the RWQCB was clearly aware of this assessment (indeed, *components* of this report are discussed in the RWQCB’s technical report, but the results of their risk assessment are omitted altogether).

There is no reason why the RWQCB could not have used the site-specific data gathered in this earlier study to provide more informed risk estimates in their Tier II assessment. The SDCDHS Health Risk Study was the first to specifically address whether “portions of the Bay currently pose any health risks to humans through the consumption of chemically contaminated fish” (County of San Diego, 1990; p. I-5). Fish samples were collected throughout the bay, and a year-long angler survey was conducted to understand the demographics and fish consumption habits of the local angling population. In the course of this study, a review panel was organized “in order to guide the development of the work program and the critical analyses of the study results” (County of San Diego, 1990; p. I-6). Overall, the panel contained 20 members, two of whom were from the RWQCB.

In short, the RWQCB has thus far completed only the first step of an iterative risk assessment process (a screening analysis). Therefore, in my opinion the risk estimates presented by the RWQCB do not reflect reality and should not serve as a basis for regulatory decision-making. Indeed, as described further below, the use of more realistic and appropriate assumptions yields human health risk estimates that are below the levels that typically warrant regulatory action.

- 2. Most of the key exposure assumptions and estimates used in the RWQCB “Tier II” assessment are implausible, biased, and inconsistent with the regulatory guidance documents that they claim to follow. The RWQCB relied on worst case point estimates and no attempt was made to describe a range of plausible risk estimates through the use of data distributions or alternative point estimates. As a result, the RWQCB deterministic risk estimates are not informative and they contain such a large degree of compounded conservatism that they are not a valid basis for decision-making purposes.**

There are several assumptions used in the RWQCB’s assessment that I believe are inappropriate and result in a significant overestimation of risk. These are specifically described below.

- a) There is no basis for assuming that a subsistence angler would only consume entire fish or shellfish**

As described in the RWQCB assessment, recreational anglers are “sport” anglers who do not rely on caught fish to supplement their diet. Conversely, subsistence anglers are typically defined as individuals who rely on caught fish for most or all of the protein in their diets ((USEPA 1998); p. 2-21). In practice, subsistence anglers are distinguished from recreational anglers by the *total daily amount of edible fish tissue* they are likely to consume. For example, the current default EPA assumption for recreational and subsistence anglers is 2 and 6.8 g/day of the *edible portions* of caught fish ((USEPA, 1997); Table 10-52). However, in their assessment, the RWQCB assumed that the *subsistence angler would always consume the entire fish (sand bass) or shellfish (lobster), skin, guts, filter organs, and all*, and not just the filet or edible portion.

This is a critical (yet baseless) assumption that serves to artificially inflate the RWQCB risk estimates. It is well known that fat-soluble contaminants are typically present at higher concentrations in the fat, skin, and internal organs of fish than they are in the leaner muscle tissue (Wilson, Shear et al. 1998). Many anglers choose to remove the skin of the caught fish prior to cooking and consumption (this is common for scaleless species such as catfish), and this typically will reduce the amount of fish tissue contaminants that are consumed. Certainly, it is possible that an angler may cook a fish with the skin intact and consume what is commonly termed a “skin-on filet.”

There may even be occasional instances where a fish or shellfish is consumed whole (such as in a stew). But it is patently absurd for the RWQCB to assume an angler will consume an entire fish (head, entrails, fins, bones, etc) every day for 30 years (In fact, it was reported in the San Diego Bay Health Risk Study that the average fishing frequency of Bay anglers was 6.4 times per month; only 6% of anglers reported fishing on a daily basis. This study did not distinguish between recreational and subsistence anglers (County of San Diego, 1990); p. xviii). The use of

the whole body data is made even more disconcerting by the fact that the assumption was not necessary, i.e., the RWQCB was not constrained to using whole body data because there was an abundant amount of edible tissue data available in the Exponent report (2003) for the two species being considered: lobster and sand bass.

A review of the fish and shellfish tissue data collected from the NASSCO leasehold indicates that the use of whole body data, instead of edible tissue data, increased the estimated risks for the subsistence angler by at least an order of magnitude. For example, I found that the use of whole body tissue data instead of edible tissue data increased the total risk of cancer (for PCBs and inorganic arsenic) by approximately 20 to 30-fold for fish. I found this to be the case whether I used maximum or mean chemical concentrations.

Furthermore, the lobster edible tissue data actually included the hepatopancreas. This is a filter organ that is highly fatty and tends to bioaccumulate chemicals at concentrations far beyond those measured in the actual edible muscle. It is rarely consumed and not typically considered to meet the definition of “edible tissue” for an angler. Use of these data represents another level of conservatism that overestimates the human health risks associated with lobster consumption.

I can see only three possible justifications for the RWQCB’s assumption of whole body (and only whole body) consumption for subsistence anglers:

1. There is regulatory guidance or published literature that recommends this assumption,
2. There is site-specific information that supports the use of this assumption, and/or
3. The stated purpose of collecting the whole body data was for use in a human health risk assessment.

Regarding item #1, EPA guidance for *screening analyses* of fish consumption risk specifically recommends the use of tissue data derived only from the edible portions of uncooked fish. For example:

“Composites of skin-on filets (except for catfish and other scaleless species, which are usually prepared as skin-off filets) and edible portions of shellfish are recommended for contaminant analyses *in screening studies* to provide conservative estimates of typical exposures for the general population. If consumers remove the skin and fatty areas from a fish before preparing it for eating, exposures to some contaminants can be reduced” ((USEPA 2000a); p. 2-4). [emphasis added]

In short, EPA acknowledges that analyzing skin-on filets will yield conservative estimates of tissue concentrations, and that these data should be considered in *screening analyses*. Skin-off filets will yield more refined and accurate estimates of risk for anglers who skin their fish prior to consumption. In my review of the regulatory literature, I evaluated several EPA guidance documents that specifically address subsistence fish consumption rates:

- USEPA, 2009. External Review Draft Exposure Factors Handbook: 2009 Update. Chapter 10. Intake of Fish and Shellfish.

- USEPA, 2000. Guidance for Assessing Chemical Contaminant Data for Use in Fish Advisories. Volume 1. Fish Sampling and Analysis. Third Ed.
- USEPA, 1997. Exposure Factors Handbook. Chapter 10. Intake of Fish and Shellfish.
- USEPA, 1991. Risk Assessment Guidance for Superfund. Appendix L: Supplemental Guidance to RAGS: Supplemental Default Values

None of these documents (nor the 1989 EPA RAGS document cited by the RWQCB) recommend the use of only whole fish/shellfish concentrations when estimating risk to the subsistence angler.

Regarding item #2, there is no site-specific information offered in the RWQCB analysis to support the assumption that a subsistence angler would consistently (daily, for 30 years) consume whole fish caught from within the NASSCO leasehold, or from any waterways directly outside of the NASSCO leasehold. In fact, this is impossible due to the security measures in place at the leasehold.

More importantly, there is no justification for the assumption that 100% of subsistence anglers would consume the whole fish or shellfish. I note that the RWQCB does cite the aforementioned SDCDHS Health Risk Study (County of San Diego 1990), wherein the authors reported (Appendix J, Table J-10) that “approximately 40% of the Filipinos and Asians eat the entire fish” (note that the RWQCB assessment does not cite the SDCDHS Health Risk Study as the basis for their assumption of whole body consumption).

There are several reasons why this observation, even if it was accurate at the time, is not a valid justification for the assumption of whole body consumption in the RWQCB risk assessment. First, the Health Risk Study *did not report that subsistence anglers consume whole fish*; this was an assumption made by the authors of the RWQCB assessment. In fact, the Health Risk Study did not report the existence of subsistence anglers at all. Second, the Health Risk Study clearly showed that the parts of the fish consumed varied by ethnicity. Even among the groups with the highest percentage reporting to eat the entire fish (Filipinos and Asians), this value was only 40%. Indeed, when all ethnicities were combined, only 25% of the entire angling population reported eating the entire fish.

As an example, using the RWQCB exposure assumptions for a subsistence angler (but replacing maximum measured whole body concentrations with mean whole body concentrations) yields a total cancer risk of 1.01×10^{-3} if it was assumed that anglers ate the entire fish (guts and all) 100% of the time. However, if it is assumed that subsistence anglers ate the entire fish 5% of the time and only the edible portions 95% of the time, the cancer risk estimate decreases 100-fold to 6.09×10^{-5} .

Third, and perhaps most importantly, while the Health Risk Study did collect information regarding which parts of the fish caught *during that particular fishing trip* the angler was planning to consume, there was no way to determine whether the angler always consumed the whole fish or if he/she was only planning to do so on the day they were interviewed. In other words, there is no information in the Health Risk Study that describes *how often* the angler chose to consume the whole fish.

The RWQCB assessment assumed, with no justification, that it was 100% of the catch, i.e., every single caught fish and lobster was consumed whole. It would have been far more plausible to have assumed that whole body fish or shellfish comprised some fraction of the subsistence or recreational angler diet, rather than the entire diet of a subsistence angler. In fact, the frequency distribution of the parts consumed by ethnicity is provided in an Appendix J of the San Diego Bay Health Risk Study. Thus, the RWQCB could have provided a more meaningful estimate but chose not to do so.

Finally, regarding item #3, I will note that the fish whole body data were collected for use in an ecological risk assessment, not a human health risk assessment. The RWQCB technical report and the Revised Tentative Cleanup and Abatement Order No. R9-2011-0001 both describe three separate assessments related to the following: 1) aquatic life, 2) aquatic-dependent wildlife, and 3) human health beneficial uses. While not the focus of my report, I reviewed these sections of the RWQCB report and Order, as well as a report prepared by Exponent and found that spotted sand bass were also collected as a part of the aquatic-dependent wildlife risk assessment (Exponent 2003; CRWQCB 2010b; CRWQCB 2010a)

The use of whole body tissue data is valid under these circumstances because the results were used in a food-web exposure model to estimate the potential impact on animals (specifically, California brown pelicans and sea lions, who may routinely consume medium-sized fish as a part of their diet). Obviously, pelicans and sea lions would not limit their consumption to filets, which is why whole body tissue samples were collected and used for this type of assessment. The Exponent report clearly states that “consistent with guidance provided by OEHHA (Brodberg, 2002), only the edible portions of fish and lobster tissue were evaluated for the main part of the human health assessment” ((Exponent 2003); p. 11-7). At no point in their report does the RWQCB explain why they thought it was appropriate to use tissue data intended for an ecological risk assessment in a human health risk assessment, particularly when edible tissue data were available.

In summary, the RWQCB’s assumption that subsistence anglers would consume entire fish and/or shellfish following each and every trip (instead of just eating the edible portion) has resulted in risk estimates for subsistence anglers that are too high by at least an order of magnitude. It is clear that the RWQCB made no effort to determine 1) whether there are any subsistence anglers that fish in or near the NASSCO leasehold, and 2) if there are, do they eat whole fish, and if so, how often? Had they done so, based on this information, they could have assumed that a subsistence angler consumed some fraction of their catch (e.g., 5%) as whole fish or shellfish and used a weighted mean for the concentration term.

b) The use of maximum chemical concentrations to represent tissue chemical concentrations yields a biased and potentially inaccurate estimate of health risk

Despite the fact that multiple samples were collected at each sampling location, the RWQCB assessment relies entirely on maximum measured chemical concentrations to estimate risks for both the subsistence angler and the recreational angler. This is even true for the “comprehensive Tier II analysis.” Indeed, it appears that no effort was made to develop any statistical metric of

the range of measured concentrations. Instead, the RWQCB selected the highest measured concentrations and presented the subsequent risk estimates as plausible and representative.

This was an arbitrary assumption with no scientific or regulatory support. No discussion is offered in the RWQCB assessment as to why use of the maximum, and only the maximum measured levels, is appropriate in this case. Reliance on a single point estimate of chemical concentration also gives no insight as to the potential variability in the risk estimates as a function of the range and frequency of measured contaminant levels. In essence, each of the risk estimates presented by the RWQCB relies on a single measured (in this case, maximum) value, which can yield a highly biased risk estimate, particularly if the underlying data set is skewed.

I will quote again from recent (2005) EPA risk assessment guidance:

...significant risk management decisions will often benefit from a more comprehensive assessment...such assessments *should provide central estimates of potential risks in conjunction with lower and upper bounds (e.g., confidence limits)* and a clear statement of the uncertainty associated with these estimates” ((USEPA 2005); p. 1-9 – 1-10).
[emphasis added]

At the very least, if the RWQCB wished to include a point risk estimate based on maximum concentrations they should have also presented risk estimates based on: 1) measures of central tendency (e.g., means or averages) and/or 2) distributions of the underlying measured concentrations. Indeed, in the SDCDHS Health Risk Study, risk estimates were presented based on maximum and average chemical concentrations (County of San Diego, 1990). Presenting risk estimates associated with each of these values would allow the reader to understand the relative impact of the concentrations used in the risk calculations.

c) Considering the lack of access and industrial nature of the shipyard leasehold, the use of unmodified fish consumption rates from the Santa Monica Bay Study, which was conducted in a highly accessible recreational area, is inappropriate and inconsistent with EPA guidance

In the United States, the primary sources of fish consumption information include the following: 1) per capita estimates for fishery products (disappearance into the commercial marketing system); 2) national consumption surveys (which can be on a per capita basis, or focus exclusively on fish consumers); and 3) creel-angler surveys (which can include recreational or subsistence fishers, or both) (USEPA 1997b; OEHHA 2001).

Results from one survey may not be applicable in a different setting. The most relevant sources of fish consumption data for a specific setting (e.g., San Diego Bay) are creel/angler surveys, wherein the catch/consumption habits of local anglers are assessed via interviews. These studies vary in many respects, including methodology, the target population evaluated, whether fishing occurs in fresh or marine waters, and whether consumption of commercially purchased products are included in the consumption estimates, to name a few. Obviously, a daily consumption rate determined for an angler catching/consuming pike in Lake Michigan may not be an accurate

estimate for an angler catching/consuming catfish from the Mississippi River. The importance of site-specific data is explicitly noted by EPA:

“As states increase their focus on this type of risk assessment, the need for site-specific fish... consumption surveys has become more apparent” ((USEPA 1998); p. 3-1).

“Determination of actual consumption levels can improve the accuracy of the risk assessment... local fish consumption data are preferred” ((USEPA 1998); p. 2-2).

“It is recommended here that local or regional assessments of fishery consumption be performed whenever possible to avoid possible errors inherent in extrapolating standard values for the U.S. population to distinct subpopulations” ((USEPA 1989a); p. 54).

“A theme carried through this document is to utilize local information and participation where possible... in the decision making process” ((USEPA 1996); p. iii).

“Because fish contamination, local conditions, and population characteristics are unique to each area, risk managers may choose to implement different policy options for different waterbodies” ((USEPA 1996); p. 2-6).

“It is still recommended, however, that... local information be collected regarding fish contamination and consumption patterns” ((USEPA 1996); p. 2-19).

Further, a recent updated draft of the EPA’s Exposure Factors Handbook no longer provides recommended values for subsistence fishing consumption rates because the available data is limited to certain geographic areas and/or Native American tribes. It is specifically indicated that subsistence data should be used only “if appropriate to the scenarios and populations being assessed” ((USEPA 2009); p. 10-4).

In addition, I will mention that the RWQCB suggests that NASSCO may not occupy the site in the future and future site visit usage may allow for fishing (CRWQCB 2010a). Based on my review of port plans and other such documents specific to the San Diego Bay, it does not appear as though this leasehold will be used as a recreational area in the foreseeable future. Currently, this area of the bay is designated as industrial land ((City of San Diego 2006); Figure EP-1). As such, the use of recreational fish consumption rates based on the assumption that the site “might” become more accessible is not justified. For example:

- The 2009 Port Master Plan for the San Diego Unified Port District specifically addresses marine-related industry: “Marine Related Industrial or Commercial uses shall have priority over other developments on or near the shoreline” ((Unified Port of San Diego 2009) p. 26).
- The NASSCO shipyard is located in the 10th Avenue Marine Terminal Planning District, which “is a developed, marine related industrial area of great importance to the region’s economic base...The Port Master Plan seeks to preserve and protect this unique coastal resource by limiting uses to strictly marine oriented industrial ones” ((Unified Port of San Diego 2009) p. 70).

1. *Use of Recreational Fish Consumption Data from the Santa Monica Bay Study in the RWQCB Risk Assessment*

No surveys have been conducted specifically in the NASSCO leasehold area that would permit derivation of site-specific fish consumption rates and, therefore, it is necessary to rely on data collected in similar settings. Numerous site-specific creel/angler surveys have been conducted in the U.S. over the past 10-20 years, including the aforementioned 1990 survey of fish consumption patterns in San Diego Bay. However, for reasons that are not adequately explained in their report, the RWQCB based their fish consumption rates on a creel/angler survey conducted in 1991-1992 in the Santa Monica Bay.

In the Santa Monica Bay survey, the study area extended from Point Dume to Cabrillo Pier and included recreational anglers from four fishing modes: piers and jetties; party boats; private boats; and beach and intertidal zone ((SCCWRP 1994); p. 3,6). Anglers were interviewed on site regarding their background, fishing history, types of fish eaten, consumption habits, and methods of preparing fish. The median consumption rate of the Santa Monica Bay anglers was 21 g/individual/day. The 95th percentile consumption rate was 161 g/individual/day. Only 39% of the anglers had caught and consumed fish from the bay during the four weeks before the interview ((SCCWRP 1994); p. 38).

I will note that OEHHA has produced a document entitled “Chemicals in Fish: Consumption of Fish and Shellfish in California and the United States” (OEHHA 2001), wherein it is stated that “ideally, it is preferable to obtain or apply regional, localized data for specific local areas of concern, particularly when the conditions differ in a substantial way. However, when adequate local data are not available, the ***results from the Santa Monica Bay study may be useful as default values for other regions in which the populations of interest and other relevant factors are similar***” ((OEHHA, 2001); p. 75) [emphasis added].

However, in the case of the NASSCO leasehold, conditions do “differ in a substantial way,” and the RWQCB did not indicate why the Santa Monica Bay fish consumption patterns are relevant. The Santa Monica Bay is one the most heavily trafficked recreational harbors in the U.S.; millions of recreators visit the beach every year and it is a highly popular location for recreational angling. In contrast, not only is the general public prohibited from entering the NASSCO leasehold via the shore (due to the presence of armed security guards and other

barriers such as buildings or 8-foot fences with razor wire), permanent obstructions in the water prevent boaters from accessing the leasehold. As mentioned previously, these measures are enforced in a number of ways, including video surveillance, requirements for identification for anyone entering or exiting the premises, alarm systems, and the use of security personnel (NASSCO 2006).

In analyzing site security, I reviewed the security footage overlooking the NASSCO facility from several months in late 2007. The footage provided 24 hour surveillance, seven days a week. The video revealed that approximately half of the security cameras view the shipyard docks and surrounding water, while half view the perimeter, entrance gates and facility property. Cameras are placed at main entrances and exits and in areas with high risk and/or high value cargo. They have the capability to monitor all perimeter barriers, water line, perimeter security boom/buoy early warning system, and numerous locations throughout the facility (NASSCO 2006).

The security cameras are functional in high and low light situations and have the ability to pan, tilt, zoom and focus manually for increased surveillance in specific areas. Increased surveillance and manual focusing were observed when activity occurred in the camera view. Throughout the viewed footage, employees were seen performing work on vessels within the facility as well as entering and exiting the perimeter. No unauthorized vessels were seen attempting to gain access to the facility waters. Additionally, no fishing or attempted fishing was observed in or around the facility. The cameras view the entire shoreline and surrounding waters and would certainly have captured fishing attempts.

Full details of how entry was made as well as accounts of why the individual was present are taken and recorded. Security remains especially strict because of NASSCO's work with naval vessels. Due to this fact, during times of threat, measures are in place to increase security and limit facility access (NASSCO 2002). Additionally, security measures are reviewed through audits and revised to remain up to date with current issues (NASSCO 2007).

The Santa Monica Bay study assessed anglers in an area where fishing is freely allowed via party or private boats, numerous piers and/or jetties, and the beach. Given the severe access restrictions of the NASSCO shipyard from land (the shore or from piers/jetties) and water (anglers on boats), it is obvious that fish consumption rates in the NASSCO leasehold are not comparable to those in Santa Monica Bay.

Finally, and perhaps most importantly, I will note that it is well understood that, like all short-term creel/angler surveys of highly populated areas, the Santa Monica Bay angler data have a significant source of bias that must be accounted for before the data can properly be used to estimate angler consumption rates for risk assessment purposes. The bias is known as "avidity bias," which refers to the fact that that repeat anglers, who are more likely to be interviewed, have higher consumption rates than those who visit the area less frequently. In short-term surveys where anglers are interviewed on multiple occasions (such as the Santa Monica Bay, a 28-day study), probability factors are typically applied to counter this bias. The Santa Monica Bay data were not adjusted for this bias before they were published, and proper adjustment for avidity bias will result in daily consumption rates far lower than those presented in the Santa Monica Bay report.

In my opinion, the RWQCB could have easily followed a similar methodology. I know of two instances in which the Santa Monica Bay data have been used in risk assessments for other settings, and in both cases the risk assessment authors properly adjusted the data for bias. One is Wilson et al. (2001), wherein the data were adjusted for use in an assessment of fish consumption risks in the Palos Verdes Shelf. In that analysis, the authors derived mean and 95th percentile consumption rates of 1.9 and 7.4 g/day ((Wilson et al, 2001); p. 634). Earlier I mentioned that probabilistic risk assessments yield risk estimates that are far more informed than those obtained with point estimates; the Wilson et al. (2001) study is in fact a state-of-the-art probabilistic analysis that relies on distributions of fish consumption rates from the Santa Monica Bay data.

The other example is actually an assessment conducted by OEHHA for the San Francisco Bay ((SFEI 2000); p. 22). Like Wilson et al. (2001), OEHHA performed an avidity bias adjustment on the Santa Monica Bay data, which resulted in fish consumption rates lower than those in the Santa Monica Bay report. In short, there is ample precedence, both in the published literature and by the RWQCB's primary in-house technical resource (OEHHA), describing proper methods for adjusting the Santa Monica Bay data to counter inherent bias so that the results can be used to accurately assess fish consumption risks. It appears that RWQCB was unaware of or ignored these methods and did not cite either one of these documents.

Likewise, adjusted fish consumption rates were also used in the 1990 SDCDH Health Risk Study, as were species-specific consumption rates (San Diego County, 1990, p. IV-3 – IV-4). The relative impact of using the various fish consumption rates (i.e., bay-wide vs. species specific) is specifically addressed in the results section of the San Diego County report. In general, when species-specific consumption rates are used, risk estimates are reduced considerably based on the fact that it is unlikely that anglers would only catch and consume a single type of fish. For example, the fish consumption rate for spotted sand bass was 0.5 g/day compared to 31.2 g/day for all types of fish.

The RWQCB's use of unadjusted, unmodified Santa Monica Bay creel/angler data, unfortunately only serves to increase the health risk estimates to values that would normally only be obtained in a worst case screening analysis. The RWQCB did not offer the reader a review of the available fish consumption rates in the published literature or regulatory guidance. In my experience, it is standard and customary for regulatory agencies to provide an overview of the available data, then an explanation justifying the reason that a certain value was chosen.

In the RWQCB report there was also no attempt to examine the influence of other fish consumption rates (from other data sources) on the risk estimates, no attempt to develop a distribution of data that was inclusive of all relevant fish consumption rates, and no quantitative uncertainty or sensitivity analysis. As described below, there are in fact other point estimates of fish consumption that are far more applicable to the NASSCO leasehold.

2. Environmental Health Coalition Survey

I will note that the RWQCB assessment and the Order cite a survey conducted by a group called the Environmental Health Coalition (EHC) in support of the assertions regarding the potentially high consumption rates from the leasehold. The EHC is an environmental advocacy group, and for many reasons, their survey has several important limitations in the context of how it was used by the RWQCB.

The EHC report is based on a limited number of questionnaires conducted at three fishing sites in San Diego Bay. The survey included 10, 79 and 20 participants at the Convention Center pier, Pepper Park pier and Chula Vista pier, respectively.

It is clear from the survey questionnaire and results that the EHC survey was not conducted in a scientific manner. The survey authors did not consult any standard protocol in designing their survey. It is not clear if the EHC accounted for repeated surveys of the same individual. In a properly conducted survey, one of the first questions asked is whether or not the participant has been interviewed before (USEPA 1998; Ray, Craven et al. 2007b).

Furthermore, it is standard in a survey to establish a time frame for questionnaire responses, such as how many fish one has caught or consumed in the previous month, six months, etc. This aspect was not included in the EHC questionnaire. Leaving these questions open ended often introduces significant inaccuracies and recall bias due to lapses in memory.

In the EHC survey, no actual consumption rates were determined or discussed. There are no measures or estimations of how frequently the caught fish are consumed. Additionally, the number of meals and meal sizes are not reported in order to determine the amount of fish that is actually consumed. Similarly, no questioning regarding the species or size of fish or sampling to determine concentrations of contaminants was performed in the fish that were consumed. Without this information it is impossible to determine if individuals are actually consuming enough fish to classify them as subsistence fishers. Further, without specific information regarding the actual fish that were caught, there is no evidence that the fish had increased concentrations of contaminants or that the feeding ranges of the fish species would have led them to areas near the shipyard.

Additionally, EHC results include some estimations of fishing frequency, but preparation habits are extrapolated from common cultural practices in Filipino and Asian cultures, not individual responses. More importantly, the EHC report emphasizes the risks associated with consumption of whole fish or fish organs, yet they did not ask the survey participants if they consumed whole fish or fish organs. Similarly, the report emphasizes that not all anglers eat only the fillet of the fish, yet they never asked the participants if they fillet the fish prior to consumption. It appears that the EHC conflated “eating skin” with “eating an entire fish”, which is clearly not appropriate since many fillets are eaten with the skin on. It is inappropriate to conclude that subsistence fishing or significant exposures occur without knowing this information.

The EHC study should not be relied upon in decision making processes. Even if this study was conducted properly and consumption rates were reported, the study results would not be representative of the limited access to the NASSCO industrial leasehold. The three fishing locations at the Convention Center, Pepper Park and Chula Vista piers are public areas that are

not similar to the privatized leasehold because they contain publicly accessible piers that anglers are free to use to catch fish at any time. As mentioned elsewhere, no accessible fishing areas or piers are present at NASSCO. Therefore, if consumption rates were determined by the EHC report in these locations, they would be significantly higher than any consumption rates of fishers in the leasehold, primarily because there is no evidence of fishing in the NASSCO leasehold.

In short, I find the EHC survey to be of no use in assessing potential risks to consumers of fish from the NASSCO leasehold

3. Creel/Angler Studies in Areas Similar to the NASSCO Leasehold

As noted in EPA guidance and by OEHHA, in the absence of site-specific data it is important to base assumptions about fish consumption rates on populations that are as similar as possible to the site of interest (USEPA 1989b; USEPA 1998; USEPA 2000b; OEHHA 2001). One of the defining characteristics of the NASSCO shipyard is the lack of access. I recently co-authored several articles describing fish consumption rates in a highly urbanized area that was also characterized by limited shore and boat access. These data were generated from a year-long, site-specific creel/angler survey (CAS) that was conducted on the lower 6 miles of the Passaic River in Newark, New Jersey (the “Study Area”) between July 1, 2000 and August 31, 2001.

Not surprisingly, there was very little angling activity in the lower half of the Study Area, which is consistent with the industrial nature and lack of access of this stretch of the river, similar to the portion of San Diego Bay where the NASSCO shipyard is located. In our study, two data collection methods were used to determine the actual number, size, and species of fish that anglers caught, kept, and ate: boat-based counts of Study Area anglers (to identify all locations where fishing occurred and estimate the level of activity at every point along the shoreline) and land-based interviews (to provide detailed data on what anglers actually caught, kept, and ate). During sampling days, a boat traveled the length of the Study Area multiple times to survey any and all possible angling locations. Estimated fish consumption rates for anglers in the Study Area were 0.42 g/day (central tendency) and 1.8 g/day (95th percentile).

These rates are similar to the EPA default values for recreators (2 and 5.5 g/day for the 50th and 95th percentiles for Southern California, respectively) developed from 38,000 interviews conducted by the National Marine Fisheries Service ((USEPA 1997b); Table 10-52). It is worth noting that these EPA default values were also adjusted for avidity bias. The potential for avidity bias was also addressed in the Passaic River CAS, where the data from anglers who were interviewed more than once were consolidated into a single value in order to avoid over-representation in the dataset.

In my opinion, the consumption rates measured in the Passaic River are just as relevant, and arguably are far more relevant, to the NASSCO leasehold than the Santa Monica Bay data. Clearly, the fish consumption rates for the lower Passaic River are considerably lower than those used in the RWQCB assessment. In the Passaic River CAS, it was specifically noted by the authors that “the results of this CAS should be viewed as more applicable to represent other industrial, urban areas where site-specific data cannot reasonably be captured, rather than

applying to those areas default values based upon more abundant fisheries with easier fishing access” (Ray, Craven et al. 2007a).

d) The assumption that 4% of the measured arsenic in fish/lobster tissue is “inorganic” is unjustified and overestimates cancer risk where in fact there may be zero risk

It is well known that the form of arsenic is a critical determinant of potential cancer risk (Edmonds and Francesconi 1993). The primary type of arsenic found in fish and shellfish is the organic form, which has negligible toxicity. The percentage of inorganic arsenic in finfish and shellfish has been shown to vary. Several reviews of the literature have reported values ranging from 0-4%. As described in detail in the Exponent risk assessment (2003), according to a recent review conducted by Donohue and Abernathy (1999), 74 of 77 marine fish specimens had inorganic arsenic levels less than 4 percent of total arsenic. In shellfish, 54 of 57 specimens had inorganic arsenic levels less than 3 percent of total arsenic (Donohue and Abernathy 1999).

The RWQCB chose the highest possible point estimate (4%) with virtually no justification or discussion as to why and how this assumption might be applicable to the NASSCO leasehold (nor did they examine any alternative point estimates or distributions). The RWQCB could easily have collected and analyzed fish tissue from the NASSCO leasehold for inorganic arsenic but they did not.

Without additional data regarding the percent inorganic arsenic in the fish and shellfish considered in the RWQCB’s assessment, it is impossible to truly characterize the possible risk due to consumption of arsenic in fish or shellfish from the bay. Interestingly, the potential cancer risk due to arsenic was also evaluated in the SDCDHS analysis, but the authors chose not to include arsenic as a contaminant of concern for this very same reason (despite initially high risk estimates that were orders of magnitude higher than what was reported by the RWQCB) ((County of San Diego 1990); p. III-21). In this particular assessment, the San Diego County Health Department concluded that “because there is little data concerning either the bioavailability or the toxicity of organic arsenic compounds for animals and no data for humans, we are unable at this time to assess the significance of arsenic found in fish from San Diego Bay and its potential impact on human health” (County of San Diego 1990, p. V-12).

e) There is no basis for the assumption of a 30-year exposure duration

The RWQCB used the highest EPA default point estimate for exposure duration with no discussion, no explanation, and no justification. The RWQCB could have reviewed local census or creel angler data to develop a more accurate and site-specific estimate. They also could have explored alternative (and lower) default EPA estimates or used a distribution of estimates. Current EPA guidance recommends using an estimate of 9 years, which represents the 50th percentile (USEPA 1997a). The studies that this value are derived from reported average exposure duration times ranging from 4.6 years to 12 years (Israeli and Nelson 1992; Johnson and Capel 1992; U.S. Bureau of the Census 1993). It should be noted that the EPA is currently proposing that the default average duration be lowered to 8 years (USEPA 2009). It does not appear that the RWQCB reviewed or considered any of this information.

f) Summary

Due to the compounded conservatism inherent in the RWQCB risk assessment, it is clear that the risk estimates developed for the NASSCO leasehold are overestimated by orders of magnitude and are inappropriate for decision-making purposes. As discussed above,

- a) There is no basis for assuming that a subsistence angler would only consume entire fish or shellfish,
- b) The use of maximum chemical concentrations to represent tissue chemical concentrations yields a biased and potentially inaccurate estimate of health risk,
- c) Considering the lack of access and industrial nature of the shipyard leasehold, the use of unmodified fish consumption rates from the Santa Monica Bay Study, which was conducted in a highly accessible recreational area, is inappropriate and inconsistent with EPA guidance,
- d) The assumption that 4% of the measured arsenic in fish/lobster tissue is inorganic is unjustified, and
- e) There is no basis for the assumption of a 30-year exposure duration at this location.

In addition to the previously discussed assumptions related to fish consumption and the use of maximum tissue concentrations, the “significant” cancer risks to the *recreational* angler are driven entirely by the unsupported assumption that 4% of the arsenic in fish tissue is inorganic. The RWQCB has no evidence that this is the case and made no effort to determine whether there is any inorganic arsenic present in fish in the NASSCO leasehold.

The so-called “significant” cancer risks to the *subsistence* angler are driven by arsenic and PCBs. In addition to the aforementioned flaws in the arsenic risk estimates, all of the subsistence angler cancer risk estimates are based on several implausible exposure assumptions that have been strung together without justification: an angler visits the leasehold on a daily basis (choosing not to fish at anywhere else in the bay), bypassing armed security, catches fish and lobster that contain the maximum measured arsenic and PCB concentrations, then takes his catch home and consumes the entire fish and lobster, entrails and all.

Repeated use of conservative or “reasonable” worst-case values for exposure factors can substantially overestimate risk ((Whitmyre, Driver et al. 1992); p. 338). In fact, this can also occur when each exposure factor is “reasonable” in its own merit, but when strung together with other higher-end exposure factors leads to results that are more extreme than any of the individual values. This is certainly the case in the RWQCB’s assessment, where it may be possible to justify their overly conservative assumptions on an individual basis, but when they are all considered together as a representation of a “reasonable” or realistic scenario that is occurring over decades, this reasoning no longer holds.

EPA clearly states that high-end exposure assumptions are intended to be plausible estimates that characterize a definable, high-end segment of the exposed population (usually above the 90th percentile) (USEPA 1992; USEPA 1995). From a purely statistical perspective, combination of multiple high-end exposure factor values (e.g., 90th or 95th percentiles) can often produce results that are more extreme than any one of the individual values. As noted by EPA ((EPA 1992); p. 27):

“The term ‘worst case exposure’ has historically meant the maximum possible exposure, or where everything that can plausibly happen to maximize exposure, happens. While in actuality, this worst case exposure may fall on the uppermost point of the population distribution, in most cases, it will be somewhat higher than the individual in the population with the highest exposure. The worst case represents a hypothetical individual and an extreme set of conditions; *this will usually not be observed in the actual population.*” [emphasis added]

As I’ve noted throughout this opinion, the impacts of the various assumptions made by RWQCB are not well characterized or discussed. The RWQCB did not conduct any sort of quantitative uncertainty analysis, nor did they provide a comparison of risk estimates derived using different point estimates (e.g., mean vs. upper bound) in a deterministic risk assessment. As noted previously, the use of probabilistic techniques is an ideal method for quantifying the uncertainty associated with each of the parameters used in risk calculations, which can then be used to determine the contribution of uncertainty associated with each parameter to the overall risk estimate. In general, sources of uncertainty include measurement errors, sampling errors, variability, and the use of generic or surrogate data ((EPA 1992); p. 93). Either approach can provide a way to quantitatively understand the impact of using one value versus another.

d) A refined yet conservative risk assessment indicates that consumption of fish and shellfish from the NASSCO leasehold is not associated with an increased risk of cancer or non-cancer health effects.

Above I have given a few examples of the degree to which the RWQCB risk estimates change by simply substituting one of their highly conservative and implausible assumptions with a more reasonable assumption (i.e., a semi-quantitative sensitivity analysis). Below I present my own estimates of risk by incorporating specific refined assumptions (Tables 1-3). The purpose of this exercise is to 1) demonstrate how much uncertainty and conservatism is actually present in the RWQCB risk estimates, and 2) provide a more scientifically valid and plausible estimate of potential angler risk. This analysis is representative of the “comprehensive” assessment that the RWQCB claimed to have conducted (but did not). Specific changes include the following:

- **Use of mean and 95% upper confidence limit (UCL) fish and shellfish tissue concentrations instead of maximum values.** Risk assessments are commonly performed using a central tendency estimate (arithmetic mean), as well as the 95% upper confidence limit (UCL) of the arithmetic mean. The 95% UCL is the value that when calculated for a random data set equals or exceeds the true mean 95% of the time. Both values are often used in risk assessment because of the uncertainties that may be associated with estimating the arithmetic mean. This approach is consistent with EPA

guidance for non-screening level assessments and provides a far more informed estimate of the distribution of chemical contaminants among the local fish and shellfish populations of interest.

- **Use of fish consumption rates that reflect the lack of access and industrial nature of the NASSCO shipyard.** As noted previously, the importance of representative data is clearly described in several EPA documents, as well as OEHHA's 2001 report regarding fish consumption in California. Based on my experience and as described in several recent publications, characterizing angling and fish consumption patterns in highly urbanized areas with relatively little public access can be useful in conducting risk assessments in similar settings. The fish consumption rates of 0.42 g/day (estimate of central tendency) and 1.8 g/day (95th percentile) reported in a study of anglers in a highly industrialized waterway with limited access were used in risk calculations for recreational anglers (the 95th percentile was used as an upper bound estimate) for both fish and shellfish (Ray, Craven et al. 2007a).
- **Assume that anglers would only consume the edible portions of any fish or shellfish.** Consistent with EPA guidance, edible tissue data were used for both the recreational and upper bound scenarios.
- **Utilization of a reference dose for dietary ingestion in estimating risk from cadmium.** There is no basis for the RWQCB's use of a drinking water reference dose for cadmium considering there is a reference dose for cadmium based on ingestion. In my updated assessment, I utilized the EPA recommended reference dose for cadmium consistent with dietary ingestion.
- **Use of an exposure duration of 9 years.** I used the central estimate of 9 years for the amount of time that potential exposure could occur, as recommended by EPA guidance ((USEPA 1989b); p. 6-22).
- **Use of a cooking loss factor for PCBs.** Cooking results in a reduction in total PCBs because they accumulate in the fat. Because the reductions vary by cooking method (e.g., pan-frying, steaming, deep-frying), a weighted average of the median fish fractional loss was used for the deterministic analysis, while a distribution was used for the probabilistic analysis (Wilson, Shear et al. 1998). The fish fractional cooking loss was weighted by the probability of using each method and cooking methods were grouped according to their cooking loss distributions. For shellfish, the mean shellfish cooking loss value was calculated from averaging PCB cooking losses from steaming and boiling (with and without hepatopancreas) whole blue crab (Zabik, Harte et al. 1992).
- **Incorporation of a probabilistic risk assessment for cancer risk for PCBs (Aroclor 1260) and arsenic.** The purpose of this assessment was to quantify uncertainty associated with the exposure parameters, as well as provide a more accurate estimation of the true cancer risk using a more refined technique (i.e., Monte Carlo analysis).

I performed two sets of risk calculations. First, I used the same equations described in the RWQCB's draft technical report, but with refined assumptions (CRWQCB 2010a). This approach was used to evaluate cancer and non-cancer risks for the chemicals identified by the RWQCB.

Second, I performed a probabilistic risk assessment ("Monte Carlo analysis") to evaluate cancer risk for a subset of chemicals (arsenic and PCBs). As mentioned previously, the Monte Carlo technique can be used to derive an estimate of the distribution of exposures or doses in a population. I also used this technique to perform a quantitative uncertainty analysis.

Tissue concentration data for the contaminants of concern (sand bass and lobster) were obtained from Exponent, and were the same tissue data upon which the RWQCB's risk assessment is based. Cancer and non-cancer risk was calculated separately for inside the NASSCO leasehold, outside the NASSCO leasehold, and for the reference locations 2230 and 2240. The specific calculations and exposure assumptions are described in greater detail in Appendix A.

Results for cancer risk using a refined deterministic model are summarized in Appendix A, Tables 4 and 5. Risk estimates using mean tissue concentrations (fish or shellfish) ranged from 1.67×10^{-8} to 1.62×10^{-6} for inorganic arsenic and from 1.17×10^{-8} to 1.62×10^{-7} for PCBs. Using the 95% UCL tissue concentrations, risk estimates ranged from 1.85×10^{-8} to 2.58×10^{-6} for inorganic arsenic and from 1.17×10^{-8} to 2.08×10^{-7} for PCBs.

As a point of comparison, if one uses my exposure assumptions but employs the method used by Exponent, wherein the more conservative fish consumption rates used by the RWQCB are used (21 g/day and 161 g/day for recreational and subsistence anglers, respectively) but a fractional intake factor is applied to account for the fact that only a 3.4% of the total shoreline of the San Diego Bay is occupied by the NASSCO shipyard, cancer risks for inorganic arsenic ranged from 2.17×10^{-7} to 7.48×10^{-6} when mean tissue concentrations were used (fish or shellfish), while cancer risk for PCBs ranged from 1.99×10^{-8} to 6.33×10^{-7} .

Furthermore, if only the fractional intake is adjusted to account for the fact that 3.4% of the total shoreline is occupied by NASSCO, all risks from all chemicals in edible tissue fall significantly below regulatory concern. Using either approach, the cancer risk estimates derived using more reasonable exposure assumptions are orders of magnitude less than those reported by the RWQCB.

Based on more realistic and appropriate exposure assumptions, risk estimates for both consumption of lobster and sea bass were well below the *de minimus* risk levels of 1 in 100,000 (1×10^{-5}) defined by CalEPA (OEHHA 2006). More recently, in June, 2008, OEHHA published a report titled "Development of Fish Contaminant Goals and Advisory Tissue Levels for Common Contaminants in California Sport Fish: Chlordane, DDTs, Dieldrin, Methylmercury, PCBs, Selenium, and Toxaphene." This report addresses the general concept that "the advisory process should be expanded beyond a simple risk paradigm, as is used in criteria development, in order to best promote the overall health of the fish consumer" (p.2). In this report, OEHHA specifically states that 1×10^{-4} is an acceptable risk level when developing fish consumption advisories (OEHHA also cites several EPA regulatory criteria that rely on this same value). In

fact, this report goes as far as to state that “setting the risk level at 1×10^{-5} or 1×10^{-6} would restrict fish consumption to the extent that it could largely deny fishers the numerous health benefits that can be accrued through fish consumption” (p. 55).

Results for non-cancer risk are summarized in Appendix A, Tables 6-10. The hazard indices for all contaminants at both consumption levels were well below 1, indicating that using more realistic and appropriate exposure assumptions results in estimated daily exposures below the levels that are considered safe by the U.S. and California Environmental Protection Agencies. Even using the 95% UCL tissue concentrations for upper bound consumers, the hazard indices did not exceed 0.013, 0.012, 0.04, 0.004, and 0.0004 for inorganic arsenic, total PCBs, mercury, copper, and cadmium, respectively.

The risk assessment described above mirrors the deterministic analysis performed by the RWQCB, the only difference being the values used in the exposure assumptions. As noted previously, there are additional techniques available that provide more statistically robust and informative risk estimates. Thus, for purposes of comparison, I also performed a probabilistic analysis of the cancer risk associated with consumption of fish and shellfish caught in the NASSCO leasehold.

The probabilistic assessment addressed Aroclor 1260 and arsenic, which were the primary drivers of cancer risk in the RWQCB assessment. It should be noted that Aroclor 1260 was the only PCB mixture that had detectable concentrations. The distributions associated with each of the exposure parameters are summarized in Table 11. These were generally derived from the same sources as my refined, deterministic calculations, although the Monte Carlo analysis also included a range of values for the percent of inorganic arsenic (0-4%) and the cancer slope factor associated with Aroclor 1260 (0.07, 0.4, and 2 per mg/kg-day). Regarding the loss of PCBs through cooking, the distribution of percent losses for fish and shellfish were based on prior empirical studies and vary by cooking method (Zabik, Harte et al. 1992; Wilson, Shear et al. 1998).

The cancer risk estimates based on this analysis are presented in Table 12. Cancer risks were within the same order of magnitude across all locations considered (inside NASSCO vs. outside NASSCO vs. reference), which is consistent with my observation that there is not a statistically significant difference in fish tissue concentrations between the shipyard and the general background in the bay (described in more detail in the next opinion).

Based on the probabilistic assessment, cancer risks for Aroclor 1260 ranged from 4.69×10^{-13} to 2.17×10^{-12} (50th percentile). Risks for the extreme upper bound of the population (99th percentile) were still well below what is considered *de minimus* risk (8.55×10^{-8} to 4.82×10^{-7} for fish and shellfish, across all locations). For inorganic arsenic, risks for the 50th percentile were in the 10^{-11} to 10^{-12} range, while at the uppermost portion of the population (99th percentile), risks ranged from 4×10^{-6} to 3×10^{-7} for fish and shellfish.

In addition to preparation of additional risk estimates, the Monte Carlo technique also allows one to quantify the uncertainty associated with parameters used in the risk calculations. I will note that there was no difference in parameter sensitivity between the various locations considered

(inside NASSCO, outside NASSCO, reference). For Aroclor 1260 cancer risk, fish or shellfish ingestion rate contributed from 86.3 to 87.4% of the total variance of the risk estimates.

Exposure duration and the Aroclor 1260 cancer slope factor (CSF) contributed to total variance with exposure duration having contributions from 4.7 to 5.2% and CSF having contributions of 7.0 to 7.6%. Adult body weight and cooking method both contributed less than 0.1% to the total variance for Aroclor and arsenic cancer risks. For arsenic cancer risk, fish and shellfish ingestion contributed about 90% to the total variance with exposure duration contributing between 4.6 to 5.1% and fraction of inorganic arsenic contributing about 2.6%.

Taken together, the uncertainty analysis highlights the importance of the fish consumption rate in the overall risk assessment, and as I have described in considerable detail above, use of the most appropriate fish consumption rate (i.e., reflective of the complete lack of access to the NASSCO leasehold) is *critical* in properly characterizing risk.

Risk Characterization

I will note that my risk estimates presented above, although reasonable, are still very conservative. They are based on the following assumptions:

1. An individual will gain access to the NASSCO leasehold and catch and consume fish and shellfish tissue for 9 years,
2. The filter organs (hepatopancreas) of the lobster will always be consumed along with the edible tissue,
3. NASSCO sediments are the source of all of the chemicals in the fish/lobster, and
4. 4% of the arsenic in the fish/lobster tissue is inorganic.

Any one of these assumptions is arguably implausible. Yet even if this individual consumes fish/shellfish tissues at the highest rate (1.8 g/day) and only eats tissues containing the upper-bound (95th UCL) chemical concentrations, the risks are below levels that typically warrant regulatory concern. Finally, I will mention that PCBs are not even considered by the USEPA to be known human carcinogens (USEPA 2010).

Additionally, I will note that the risk estimates published by the County of San Diego in their Health Risk Study (the SDCDHS study) were also generally below levels of regulatory concern, particularly when more refined assumptions (e.g., average contaminant concentration values, average fish consumption rate, species-specific fish consumption rate) were used in the risk calculations. In their report, the County of San Diego concluded that “the estimated excess lifetime cancer risk resulting from a typical consumption of fish from San Diego Bay falls between the estimated risks resulting from the consumption of four tablespoons of peanut butter per day (5.6×10^{-4}) and from the average saccharin consumption in the U.S. or drinking one pint of milk per day (both at 1.4×10^{-4}) ((County of San Diego, 1990); p. xxv).

Like my refined assessment, the San Diego Bay Health Risk Study notes that a degree of conservatism remains even in their refined risk estimates: “Due to the conservative nature of

quantitative risk assessments, the actual risk may be several orders or magnitude lower or could even be zero” ((County of San Diego, 1990); p. xx).

Another common risk characterization technique involves comparisons of the estimated doses to “background” doses of the chemicals of interest. This type of analysis was clearly described in Wilson et al. (2001), wherein pharmacokinetic models were used to estimate the daily uptake of PCBs based on concentrations measured in the blood and adipose tissue. A back-calculation was performed in order to determine the amount of PCBs that would have to be consumed in the diet to correspond to levels measured in the blood and/or tissues of the American general population, which were reported to be 5 µg/kg in blood serum and 0.82 mg/kg in adipose tissue (Wilson, Price et al. 2001).

Assuming a half-life of seven years, one would need to consume 44 ng/kg-d of PCBs in order to achieve and maintain 6 µg/kg in the blood serum. As a point of comparison, the mean estimated lifetime average daily dose for recreational anglers consuming fish from the NASSCO leasehold was 0.0251 ng/kg-d, while the upper end estimate was 0.108 ng/kg-d. These doses are equivalent to 0.06% and 0.25% of the background doses received from dietary sources.

- e) **The RWQCB’s risk assessment and the Tentative Order fail to acknowledge that the fish/shellfish contaminant levels measured in the NASSCO leasehold are 1) statistically indistinguishable from those measured outside the leasehold, including the background reference locations specifically selected by the RWQCB, and 2) for PCBs, no different from background levels that have been measured around the U.S. Clearly, such findings are inconsistent with the assertions that NASSCO operations are a “chemical source” or that remediation of NASSCO sediments will reduce human health risk.**

It is important to note that all of the chemicals of interest in the San Diego Bay risk assessments are ubiquitous and are typically present at measurable levels in sediments and fish tissues. This is obviously true for the metals, all of which occur naturally, but is also true for PCBs, which bioaccumulate easily and do not degrade quickly in the environment. Accordingly, the mere presence of metals or Aroclor 1260 in NASSCO fish tissues does not indicate that NASSCO is the source of these chemicals; I believe these chemicals would be present at measurable levels even if NASSCO had never conducted operations in the leasehold.

A statistical comparison of the mean chemical concentrations measured in edible fish and lobster tissues collected inside the NASSCO leasehold vs. those measured at reference locations indicates no significant difference (Tables 13 and 14). By definition, a chemical “source” results in levels of environmental contaminants that are higher than regional and/or national background levels. However, the fish tissue data collected from the NASSCO leasehold are no different from tissue concentrations collected in the selected reference station, which strongly suggests that the discharges from the leasehold do not appear to have influenced fish tissue concentrations.

I will note that the reference locations were specifically chosen by the RWQCB to represent “background.” Further, the mean chemical concentrations measured in the edible fish tissues

collected inside the NASSCO leasehold vs. those measured at the nearby “outside NASSCO” location (outside but adjacent to the leasehold) are not statistically significantly different (Table 14). Finally, the mean concentrations of fish tissue concentrations measured “outside NASSCO” vs. the reference concentrations are not statistically significantly different (Table 14). In short, the fish tissue concentrations throughout San Diego Bay are the same, regardless of location and, hence, appear to be representative of regional background concentrations.

Similarly, in the County of San Diego Health Risk Study, PCB concentrations in muscle tissue did not vary significantly by location (San Diego County, 1990; Table IV-I). Sampling locations in this study included Harbor Island, Shelter Island, and the Embarcadero/Coronado Bridge area. The Embarcadero/Coronado Bridge location is approximately a half-mile from the NASSCO shipyards. Average and maximum concentrations reported for Aroclor 1260 were 79.5 ppb and 173 ppb, respectively (San Diego County, 1990; Table IV-H). These values are higher than the 95th UCL values reported inside the NASSCO shipyard for edible tissue (42.77 ppb), which clearly suggests that PCBs are ubiquitous throughout the entire bay.

This is consistent with the fact that the tissue chemical concentrations from within the leasehold are similar to levels that have been measured throughout Southern California. For example, PCB levels in fish tissues were reported in studies conducted around the Palo Verdes Shelf in Southern California. In one study, wherein fish were collected at 24 sites in Southern California, mean PCB concentrations (sum of Aroclors 1254 and 1260) reported were 17 ppb for Pacific barracuda, 31 ppb for barred sand bass, and 5.7-24 ppb for chub mackerel (Pollack, Uhaa et al. 1991).

In a separate study, average PCB concentrations ranged from 50 ppb (kelp bass) to 1700 ppb (white croaker) (Los Angeles County Sanitation District 1997), as cited in Wilson et al, 2001). I also analyzed an EPA database that houses fish tissue concentration data for California lakes and reservoirs: Aroclor 1260 values ranged from 7.84 to 15.54 ppb among predatory fish and from 4.46 to 235.6 ppb for bottom dwelling fish (USEPA 2007). As another point of comparison, the U.S. Food and Drug Administration (FDA) Action Level for PCBs is 2 parts per million (ppm), or 200 ppb, “in fish and shellfish (edible portion). The edible portion of fish excludes head, scales, viscera, and inedible bones” (US FDA 2007). The 95th percentile values calculated for inside/outside the NASSCO leasehold (as well as the reference location) ranged between 42.77 to 49.18 ppb, well below the FDA action level.

The RWQCB should have explicitly acknowledged the fact that there is no statistical difference between fish and shellfish tissue concentrations inside the leaseholds and the reference locations and the implications thereof, which include the following:

1. The RWQCB has failed to indicate how the existing data are consistent with NASSCO as a chemical source,
2. The RWQCB has failed to acknowledge that in fact the data indicate that NASSCO discharges do not appear to have influenced fish tissue concentrations, and
3. The estimated cancer and non-cancer risks associated with regional “background” tissue concentrations contribute significantly to the risks developed for the NASSCO leasehold.

Again, it should be emphasized that the similarity across sampling locations for PCBs is consistent with what has been reported in the past in other surveys (County of San Diego, 1990; Table IV-I). With respect to #3, Tables 4-10 summarize the risks I have calculated for the reference, “inside NASSCO,” and “outside NASSCO” locations. The risks calculated for locations outside the NASSCO leasehold (reference and “outside NASSCO” locations) are always a significant fraction of the “inside NASSCO” risks and in fact in many cases (e.g., for Arcolor 1260) the risks *always* exceed those in the leasehold.

Clearly, these findings are inconsistent with the RWQCB’s apparent belief that remediation of sediments in the NASSCO leasehold will yield meaningful reduction in potential health risks associated with consumption of fish from the San Diego Bay. .

V. CLOSING COMMENTS

I submit these opinions and am prepared to support them in both deposition and/or courtroom testimony. I may supplement this report if additional information becomes available or I am asked to address other issues.

Respectfully,



March 11, 2011

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Date

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List of Acronyms

CAS	Creel angler survey
EHC	Environmental Health Coalition
EPA	U.S. Environmental Protection Agency
FDA	U.S. Food and Drug Administration
NASSCO	National Steel and Shipbuilding Company
OEHHA	Office of Environmental Health Hazard Assessment
PCBs	Polychlorinated biphenyls
RWQCB	Regional Water Quality Control Board
SDCDHS	San Diego County Department of Health Services
UCL	Upper confidence level

Appendix A

Supplemental Equations and Tables

Appendix A

Human exposure to contaminants in fish and shellfish was estimated using the following exposure model consistent with U.S. EPA guidance (CRWQCB 2010a).

$$\text{Intake (mg/kg-day)} = (C \times CR \times FI \times ED \times EF \times (1-CL)) / (BW \times AT \times CF)$$

Where:

- C = Tissue chemical concentration in spotted sand bass and spiny lobster (µg/kg-wet weight)
- CR = Fish consumption rate (kg/day)
- FI = Fraction ingested from the site (unitless)
- ED = Exposure duration (years)
- EF = Exposure frequency (days/year)
- BW = Body weight (kg)
- AT = Averaging time (days)
 - non- carcinogens: 30 years x 365 days
 - carcinogens: 70-year lifetime x 365 days
- CF = Conversion factor (1000µg/mg)
- CL = Cooking loss reduction (applicable for PCBs only)

The exposure assumptions used can be found below in Table 1.

Table 1. Exposure Assumptions for Anglers.

Parameter	Abbreviation	Units	Recreational Angler	Upper Bound Angler
Tissue Chemical Concentration	C	µg/kg	Refer to Table 2	Refer to Table 2
Fish or Shellfish Consumption Rate	CR	kg/day	0.00042	0.0018
Body Weight	BW	Kg	70	70
Exposure Duration	ED	Years	9	9
Exposure Frequency	EF	days/year	365	365
Fraction Ingested from Site or Reference	FI	Unitless	1	1
Averaging Time for Carcinogens	At _c	Days	25,550	25,550
Averaging Time for Non-carcinogens	AT _n	Days	10,950	10,950
Conversion Factor	CF	µg/mg	1000	1000
Cooking loss (fraction) median – fish	CL	Unitless	0.359	0.359
Cooking loss (fraction) mean – shellfish	CL	Unitless	0.309	0.309

The average and 95 % UCL fish and shellfish exposure point concentration values are reported below in Table 2.

Table 2. Exposure Point Concentrations^a

Location of Exposure	Chemical					
	Arsenic ^b	Aroclor 1254	Aroclor 1260	Mercury	Cadmium	Copper
Mean Tissue Concentration Value – Spotted Sand Bass (µg/kg)						
Inside NASSCO	14.4	ND	32.6	123.8	ND	190
Outside NASSCO	16.8	ND	38.2	148	ND	144
Reference location	14.4	ND	32.8	192	ND	134
95% UCL Tissue Concentration Value – Spotted Sand Bass (µg/kg)						
Inside NASSCO	16*	ND	42.77	160.4	ND	294.4
Outside NASSCO	20	ND	49.18	166.3	ND	167.9
Reference location	16	ND	47.8	241.7	ND	180
Mean Tissue Concentration Value -- Shellfish (µg/kg)						
Inside NASSCO	326	ND	11	251	30.25	14000
Outside NASSCO	N/A	N/A	N/A	N/A	N/A	N/A
Reference location	158.4	ND	12.6	85.4	12.2	16600
95% UCL Tissue Concentration Value -- Shellfish (µg/kg)						
Inside NASSCO	520*	ND	11*	520	50*	14000
Outside NASSCO	N/A	N/A	N/A	N/A	N/A	N/A
Reference location	176	ND	15	102.8	21.61	19000

N/A=Not applicable (no shellfish samples collected “Outside NASSCO”); ND=non-detect (all samples reported as less than the limit of detection; UCL=Upper confidence limit of the mean

^aProUCL 4.0 was used for all data analyses (USEPA, 2007). The data were grouped into uncensored and censored data sets. For uncensored data sets, because sample sizes were small (N ≤ 5) and because the distributions of each data set were found to be reasonably symmetric, the 95UCL on the population mean was estimated using Student’s-t distribution. For censored data sets, the Kaplan-Meier method was used to estimate the population mean. The 95UCL on the population mean was estimated using the Kaplan-Meier method based on Student’s-t-distribution.

^bInorganic arsenic is assumed to be 4% of the total.

*Calculated 95% UCL was higher than the maximum value. Maximum value used in risk calculations

Risk Characterization

The following equation was used to estimate risks from exposure to the carcinogenic chemicals of concern:

$$\text{Risk} = (\text{Intake} \times \text{CSF})$$

Where:

$$\begin{aligned} \text{Intake} &= \text{Human exposure to chemical concentrations in fish and shellfish tissue (mg/kg-day)} \\ \text{CSF} &= \text{Cancer slope factor (mg/kg-day)}^{-1} \end{aligned}$$

The following equation was used to estimate risks from exposure to non-carcinogenic chemicals of concern:

$$\text{Hazard Index} = (\text{Intake} / \text{RfD})$$

$$\begin{aligned} \text{Intake} &= \text{Human exposure to chemical concentrations in fish and shellfish tissue (mg/kg-day)} \\ \text{RfD} &= \text{Reference dose (mg/kg-day)} \end{aligned}$$

Toxicity values are presented below in Table 3.

Table 3. Cancer Slope Factors and Reference Doses for Chemicals of Concern^a

Chemical	U.S. EPA CSF (1/mg/kg-d)	U.S. EPA RfD (mg/kg-d)	Cal EPA CSF (1/mg/kg-d)	Cal EPA RfD (mg/kg-d)
Arsenic, inorganic	1.50E+00	3.00E-04	-	3.00E-04
Cadmium	-	1.00E-03	-	1.00E-03
Copper	-	3.70E-02 ^c	-	-
Mercury	-	-	-	1.60E-04
Methyl mercury		1.00E-04	-	1.00E-04
Polychlorinated Biphenyls^b				
Aroclor 1260 ^d	2.00E+00	-	-	2.00E-05
Aroclor 1254	2.00E+00	2.00E-05	-	2.00E-05

^a Only arsenic and PCBs are considered in cancer risk estimates

^b For PCBs, the upper bound estimate of the CSF for Aroclor 1254 was used

^c Copper RfD is derived from the drinking water MCL (maximum concentration level)

^d Aroclor 1260 values are based on the most conservative EPA values for all PCBs

Table 4. Excess Cancer Risk for Inorganic Arsenic				
Species	Location	RWQCB Original Cancer Risk	ChemRisk Mean Tissue Concentration	ChemRisk 95% UCL Tissue Concentration
Lobster	Recreational			
	Inside NASSCO	1.00E-04	3.77E-07	6.02E-07
	Reference 2230	3.39E-05	1.83E-07	2.04E-07
	Upper Bound (95th Percentile)			
	Inside NASSCO	2.78E-04	1.62E-06	2.58E-06
	Reference 2230	4.44E-04	7.86E-07	8.73E-07
Sand Bass	Recreational			
	Inside NASSCO	3.09E-06	1.67E-08	1.85E-08
	Outside NASSCO	3.86E-06	1.94E-08	2.31E-08
	Reference 2240	3.09E-06	1.67E-08	1.85E-08
	Upper Bound (95th Percentile)			
	Inside NASSCO	3.55E-05	7.14E-08	7.93E-08
	Outside NASSCO	5.32E-05	8.33E-08	9.92E-08
	Reference 2240	2.96E-05	7.14E-08	7.93E-08

Table 5. Excess Cancer Risk for Total PCBs				
Species	Location	RWQCB Original Cancer Risk	ChemRisk Mean Tissue Concentration	ChemRisk 95% UCL Tissue Concentration
Lobster	Recreational			
	Inside NASSCO	5.14E-06	1.17E-08	1.17E-08
	Reference 2230	5.14E-06	1.34E-08	1.60E-08
	Upper Bound (95th Percentile)			
	Inside NASSCO	1.50E-04	5.03E-08	5.03E-08
	Reference 2230	8.08E-05	5.76E-08	6.85E-08
Sand Bass	Recreational			
	Inside NASSCO	1.18E-05	3.22E-08	4.23E-08
	Outside NASSCO	1.47E-05	3.78E-08	4.86E-08
	Reference 2240	1.41E-05	3.24E-08	4.72E-08
	Upper Bound (95th Percentile)			
	Inside NASSCO	4.14E-03	1.38E-07	1.81E-07
	Outside NASSCO	1.18E-03	1.62E-07	2.08E-07
	Reference 2240	1.10E-03	1.39E-07	2.02E-07

Table 6. Non-Cancer Risk (Hazard Index) for Inorganic Arsenic*				
Species	Location	RWQCB Original Hazard Index	ChemRisk Mean Tissue Concentration	ChemRisk 95% UCL Tissue Concentration
Lobster	Recreational			
	Inside NASSCO	--	1.96E-03	3.12E-03
	Reference 2230	--	9.50E-04	1.06E-03
	Upper Bound (95th Percentile)			
	Inside NASSCO	--	8.38E-03	1.34E-02
	Reference 2230	--	4.07E-03	4.53E-03
Sand Bass	Recreational			
	Inside NASSCO	--	8.64E-05	9.60E-05
	Outside NASSCO	--	1.01E-04	1.20E-04
	Reference 2240	--	8.64E-05	9.60E-05
	Upper Bound (95th Percentile)			
	Inside NASSCO	--	3.70E-04	4.11E-04
	Outside NASSCO	--	4.32E-04	5.14E-04
	Reference 2240	--	3.70E-04	4.11E-04
*Based on US EPA RfD				

Table 7. Non-Cancer Risk (Hazard Index) for Total PCBs*				
Species	Location	RWQCB Original Hazard Index	ChemRisk Mean Tissue Concentration	ChemRisk 95% UCL Tissue Concentration
Lobster	Recreational			
	Inside NASSCO	NC	6.84E-04	6.84E-04
	Reference 2230	NC	7.84E-04	9.33E-04
	Upper Bound (95th Percentile)			
	Inside NASSCO	8.74E+00	2.93E-03	2.93E-03
	Reference 2230	4.72E+00	3.36E-03	4.00E-03
Sand Bass	Recreational			
	Inside NASSCO	6.90E-01	1.88E-03	2.47E-03
	Outside NASSCO	8.55E-01	2.20E-03	2.84E-03
	Reference 2240	8.25E-01	1.89E-03	2.76E-03
	Upper Bound (95th Percentile)			
	Inside NASSCO	2.42E+02	8.05E-03	1.06E-02
	Outside NASSCO	6.90E+01	9.44E-03	1.22E-02
	Reference 2240	6.44E+01	8.10E-03	1.18E-02

*Based on US EPA RfD

For Total PCBs, ChemRisk values are Aroclor 1260 values. Aroclor 1254 was not detected in tissue samples.

Table 8. Non-Cancer Risk (Hazard Index) for Cadmium*				
Species	Location	RWQCB Original Hazard Index	ChemRisk Mean Tissue Concentration	ChemRisk 95% UCL Tissue Concentration
Lobster	Recreational			
	Inside NASSCO	NC	5.45E-05	9.00E-05
	Reference 2230	NC	2.34E-05	3.89E-05
	Upper Bound (95th Percentile)			
	Inside NASSCO	8.28E-01	2.33E-04	3.86E-04
	Reference 2230	8.74E-01	1.00E-04	1.67E-04
Sand Bass	Recreational			
	Inside NASSCO	NC	ND	ND
	Outside NASSCO	NC	ND	ND
	Reference 2240	NC	ND	ND
	Upper Bound (95th Percentile)			
	Inside NASSCO	NC	ND	ND
	Outside NASSCO	NC	ND	ND
Reference 2240	NC	ND	ND	
*Based on US EPA RfD				
ND (None Detected): Cadmium was not detected in Fish tissue samples at any location				
NC (Not Calculated): RWQCB did not calculate a risk value				

Table 9. Non-Cancer Risk (Hazard Index) for Copper					
Species	Location	RWQCB Original Hazard Index	ChemRisk Mean Tissue Concentration	ChemRisk 95% UCL Tissue Concentration	
Lobster	Recreational				
	Inside NASSCO	NC	6.81E-04	6.81E-04	
	Reference 2230	NC	8.08E-04	9.24E-04	
	Upper Bound (95th Percentile)				
	Inside NASSCO	4.16E+00	2.92E-03	2.92E-03	
	Reference 2230	4.10E+00	3.46E-03	3.96E-03	
Sand Bass	Recreational				
	Inside NASSCO	NC	9.24E-06	1.43E-05	
	Outside NASSCO	NC	7.01E-06	8.17E-06	
	Reference 2240	NC	6.52E-06	8.76E-06	
	Upper Bound (95th Percentile)				
	Inside NASSCO	NC	3.96E-05	6.14E-05	
	Outside NASSCO	NC	3.00E-05	3.50E-05	
Reference 2240	NC	2.79E-05	3.75E-05		
*Based on US EPA RfD					
NC (Not Calculated): RWQCB did not calculate a risk value					

Table 10. Non-Cancer Risk (Hazard Index) for Total Mercury*				
Species	Location	RWQCB Original Hazard Index	ChemRisk Mean Tissue Concentration	ChemRisk 95% UCL Tissue Concentration
Lobster	Recreational			
	Inside NASSCO	1.56E+00	4.52E-03	9.36E-03
	Reference 2230	3.30E-01	1.54E-03	1.85E-03
	Upper Bound (95th Percentile)			
	Inside NASSCO	1.36E+00	1.94E-02	4.01E-02
	Reference 2230	1.98E+00	6.59E-03	7.93E-03
Sand Bass	Recreational			
	Inside NASSCO	NC	2.23E-03	2.89E-03
	Outside NASSCO	NC	2.66E-03	2.99E-03
	Reference 2240	NC	3.46E-03	4.35E-03
	Upper Bound (95th Percentile)			
	Inside NASSCO	4.14E+00	9.55E-03	1.24E-02
	Outside NASSCO	4.60E+00	1.14E-02	1.28E-02
	Reference 2240	3.68E+00	1.48E-02	1.86E-02
*Based on US EPA RfD				
NC (Not Calculated): RWQCB did not calculate a risk value				

Table 11. Probabilistic Risk Assessment Exposure Parameters

Parameter	n	Units	Distribution	PDF Parameters	Reference
Tissue Chemical Concentration - Arsenic					
Shellfish - Inside NASSCO	Cshellin	ug/kg	Bootstrap	mean = 144; stdev = 96.2; 95% ile=323	
Shellfish - Reference location	Cshellref	ug/kg	Bootstrap	mean = 91.3; stdev = 52.8; 95% ile=174	
Fish - Inside NASSCO	Cfishin	ug/kg	Bootstrap	mean = 7.7; stdev = 4.5; 95% ile=14.7	
Fish - Outside NASSCO	Cfishout	ug/kg	Bootstrap	mean = 9.4; stdev = 5.4; 95% ile=17.7	
Fish - Reference location	Cfishref	ug/kg	Bootstrap	mean = 7.7; stdev = 4.5; 95% ile=14.8	
Tissue Chemical Concentration - Aroclor 1260					
Shellfish - Inside NASSCO	Cshellin	ug/kg	Bootstrap	mean = 7.0; stdev = 1.4; 95% ile=9.5	
Shellfish - Reference location	Cshellref	ug/kg	Bootstrap	mean = 9.2; stdev = 1.9; 95% ile=12.4	
Fish - Inside NASSCO	Cfishin	ug/kg	Bootstrap	mean = 36.3; stdev = 3.1; 95% ile=41.2	
Fish - Outside NASSCO	Cfishout	ug/kg	Bootstrap	mean = 39.8; stdev = 5.0; 95% ile=48.2	
Fish - Reference location	Cfishref	ug/kg	Bootstrap	mean = 23.7; stdev = 5.9; 95% ile=33.0	
Fish or Shellfish Consumption Rate	CR	kg/day	Lognormal	mean=0.00042; 95% ile=0.0018	Ray et al., 2007
Fish Cooking Method			Empirical	Raw=0.03; Smoke=0.007; Bake=0.044; Boil=0.088; Broil=0.168; Fry=0.663	Wilson et al., 1998
Fraction of PCBs lost to cooking for fish - Raw	CL_Raw_fish	unitless	Point Estimate	0	Wilson et al., 1998
Fraction of PCBs lost to cooking for fish - Smoke	CL_Smoke_fish	unitless	Empirical	5% ile=0.054; 50% ile=0.37; 95% ile=0.89	Wilson et al., 1998
Fraction of PCBs lost to cooking for fish - Bake	CL_Bake_fish	unitless	Empirical	5% ile=0.036; 50% ile=0.25; 95% ile=0.89	Wilson et al., 1998
Fraction of PCBs lost to cooking for fish - Boil	CL_Boil_fish	unitless	Empirical	5% ile=0.037; 50% ile=0.68; 95% ile=0.94	Wilson et al., 1998
Fraction of PCBs lost to cooking for fish - Broil	CL_Broil_fish	unitless	Empirical	5% ile=0.071; 50% ile=0.40; 95% ile=0.90	Wilson et al., 1998
Fraction of PCBs lost to cooking for fish - Fry	CL_Fry_fish	unitless	Empirical	5% ile=0.044; 50% ile=0.33; 95% ile=0.88	Wilson et al., 1998
Fraction of PCBs lost to cooking for shellfish - Boil	CL_Boil_shellfish	unitless	Empirical	50% ile=0.31; 95% ile=0.34; 99% ile=0.36	Zabik et al., 1992
Body Weight	BW	kg	Lognormal	mean=71.0; stdev=15.9	Finley et al., 1994
Exposure Duration - residential occupancy	ED	years	Lognormal	5% ile=0.3; 50% ile=2.9; 95% ile=13.0	Finley et al., 1994
Exposure Frequency	EF	days/years	Point Estimate	365	
Fraction Ingested from Site or Reference	FI	unitless	Point Estimate	1	
Averaging Time for Carcinogens	ATc	days	Point Estimate	25,550	
Averaging Time for Noncarcinogens	ATnc	days	Point Estimate	365*ED	
Conversion Factor	CF	mg/ug	Point Estimate	1E-03	
Aroclor 1260 Cancer potency factor	CSF	/(mg/kg-day)	Bootstrap	0.07, 0.4, 2	
Fraction of arsenic as inorganic species	FAS	%	Uniform	min=0%; max=4%	

Table 12. Cancer Risk Estimates Based on Monte Carlo Analysis							
Dataset	Species	Arsenic			Aroclor 1260		
		50%ile	95%ile	99%ile	50%ile	95%ile	99%ile
NASSCO	Fish	2.4E-12	8.2E-09	3.0E-07	2.0E-12	1.1E-08	4.5E-07
Outside NASSCO	Fish	2.7E-12	1.1E-08	3.3E-07	2.2E-12	1.2E-08	4.8E-07
Reference Location	Fish	2.3E-12	8.1E-09	3.0E-07	1.3E-12	7.6E-09	2.8E-07
NASSCO	Shellfish	4.3E-11	1.5E-07	4.8E-06	4.7E-13	2.5E-09	8.6E-08
Reference Location	Shellfish	2.7E-11	9.6E-08	3.6E-06	6.3E-13	3.3E-09	1.1E-07

Table 13. Comparison of Edible Tissue Concentration in Reference Samples and Samples Collected Inside NASSCO (Lobster)												
	Arsenic (mg/kg)		Cadmium (mg/kg)		Copper (mg/kg)		Mercury (mg/kg)		Aroclor 1254 (ug/kg)		Aroclor 1260 (ug/kg)	
	Reference	Inside NASSCO	Reference	Inside NASSCO	Reference	Inside NASSCO	Reference	Inside NASSCO	Reference	Inside NASSCO	Reference	Inside NASSCO
N	5	4	5	4	5	4	5	4			5	4
Average	3.96	8.15	0.01	0.03	16.60	14.00	0.09	0.25	--	--	8.40	8
Standard Deviation	0.47	5.05	0.01	0.02	2.79	0.00	0.02	0.21	--	--	4.77	3.46
t-test p-value	0.20		0.21		0.053*		0.22		--		0.89	
Significant?	No		No		No		No		All ND		No	
All results expressed as concentration of chemical (mg or ug) per kg wet tissue												

Table 14. Comparison of Edible Tissue Concentration in Reference Samples and Samples Collected Inside and Outside NASSCO (Sand Bass)												
Samples Collected Inside NASSCO												
	Arsenic (µg/kg)		Cadmium (µg/kg)		Copper (µg/kg)		Mercury (mg/kg)		Aroclor 1254 (ug/kg)		Aroclor 1260 (ug/kg)	
	Reference	Inside NASSCO	Reference	Inside NASSCO	Reference	Inside NASSCO	Reference	Inside NASSCO	Reference	Inside NASSCO	Reference	Inside NASSCO
N	5	5	5	5	5	5	5	5	5	5	5	5
Average	0.36	0.36	ND	ND	0.13	0.19	0.19	0.12	ND	ND	30.00	32.6
Standard Deviation	0.05	0.05	--	--	0.03	0.15	0.05	0.06	--	--	19.18	10.67
t-test p-value	1.00		NC		0.47		0.08		NC		0.80	
Significant?	No		All ND		No		No		All ND		No	
Samples Collected Outside NASSCO												
	Reference	Outside NASSCO	Reference	Outside NASSCO	Reference	Outside NASSCO	Reference	Outside NASSCO	Reference	Outside NASSCO	Reference	Outside NASSCO
	N	5	5	5	5	5	5	5	5	5	5	5
Average	0.36	0.42	ND	ND	0.13	0.14	0.19	0.15	ND	ND	30.00	38.2
Standard Deviation	0.05	0.04	--	--	0.03	0.03	0.05	0.02	--	--	19.18	11.52
t-test p-value	0.09		NC		0.55		0.11		NC		0.44	
Significant?	No		All ND		No		No		All ND		No	
Samples Collected Inside and Outside NASSCO												
	Inside	Outside	Inside	Outside	Inside	Outside	Inside	Outside	Inside	Outside	Inside	Outside
	N	5	5	5	5	5	5	5	5	5	5	5
Average	0.36	0.42	ND	ND	0.19	0.14	0.12	0.15	ND	ND	32.6	38.2
Standard Deviation	0.05	0.04	--	--	0.15	0.03	0.06	0.02	--	--	10.67	11.52
t-test p-value	0.09		NC		0.55		0.38		NC		0.45	
Significant?	No		All ND		No		No		All ND		No	
All results expressed as concentration of chemical (mg or ug) per kg wet tissue												
NC=Not Calculated. All samples in both locations reported as non-detects												

Appendix B

Curriculum Vitae



Brent L. Finley, Ph.D., D.A.B.T.

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Professional Profile

Dr. Brent Finley is a board-certified toxicologist with 20 years of experience conducting and managing studies involving chemical exposures and human health risk assessment. He specializes in applied research, litigation support, regulatory negotiations, and risk-based site investigations. Dr. Finley has studied the health effects of exposure to a wide range of chemicals, including asbestos, petroleum-based products, chlorinated solvents, chromium, dioxins, and PCBs. He has provided expert witness testimony in lawsuits involving alleged health risks associated with exposures to asbestos in friction products, airborne chemicals from incinerator emissions, chlorinated solvents in groundwater, and chromium in tapwater. Dr. Finley has been involved in the preparation of more than 400 risk assessments, has published over 25 papers in the last five years, and has been an invited speaker at numerous technical seminars.

Before joining ChemRisk, Dr. Finley was the Director of Exponent's Human Health Risk Assessment practice (staff of 35) for six years. Prior to this, Dr. Finley was a staff toxicologist with Amoco Corporation. Dr. Finley's responsibilities at Amoco included the preparation of warning language for Amoco's fibers and resins product lines.

Education and Degrees Earned

Ph.D., Toxicology/Pharmacology, Washington State University, 1986
B.A., Biological Sciences, Cornell University, 1982

Certifications

Diplomate, American Board of Toxicology (1991); re-certified in 1996, 2001 and 2007

Professional Honors/Awards

Recipient of Society of Toxicology's "Outstanding Published Paper Award" (1995)
Recipient of Society of Toxicology's "Graduate Student Best Paper" Award, 3rd place (1985)
Recipient of Pharmaceutical Manufacturer's Association Research Grant (1982)

Professional Experience

Specific Experience with Benzene

Served as an expert in exposure and risk assessment in a case involving exposure to benzene in coal tar pitch volatiles in roofing tar

On behalf of a pipeline manufacturer, evaluated health claims related to household exposure to benzene vapors following an underground leak

Deposed in a case involving alleged exposures to benzene in a degreasing solvent

Conducted over 30 environmental risk assessments in which benzene in groundwater was a significant contributor to potential human health risks

Served as expert witness for Oryx Energy in a case involving property damage/health harm from a groundwater benzene plume

Specific Experience with Groundwater Risk Assessment

Involved in several cases (Aerojet, CNH) wherein current and historical residential exposure to chlorinated solvents in groundwater and tapwater is alleged. These cases involve exposure and dose reconstruction (tapwater ingestion and inhalation and dermal exposures during showering) using measured and modeled data and conclusions concerning alternative causation.

Assessed exposure to Cr(VI) in groundwater via the use of simulation studies (all subsequently published in the peer-reviewed literature) and served as a testifying expert in a case involving numerous plaintiffs in Hinkley, CA

Testified in a hearing regarding the adequacy of several atrazine databases for use in health risk assessment.

Specific Experience with Asbestos

Serving as a consultant and expert witness in a series of cases involving alleged exposure to asbestos in welding rods, joint compound and automotive and crane brake linings, clutches, and gaskets

Deposed in a premise case involving bystander exposure to asbestos-containing insulation

Published eight papers in the peer-reviewed literature pertaining to asbestos exposure, warnings, and health risks from a state-of-the art perspective

Specific Experience with Chlorinated VOCs

Deposed as an expert witness in a toxic tort case involving alleged exposure to numerous chlorinated solvents (TCE, TCA, and CCl₄) in groundwater (Comeaux v. Conde Vista). Dr. Finley reviewed the existing groundwater and soil gas data and determined, based on site-specific vapor migration modeling and an evaluation of household exposure pathways, that any inhalation exposure to chlorinated solvents that might have occurred was insufficient to cause the plaintiff's claimed health effects.

Assisted defense counsel in litigation involving alleged residential TCE exposure in the 1950s and 1960s (Stuart v. Lockheed).

Served as a panel member for the International Life Sciences Institute Working Group on estimation of dermal and inhalation exposure to chlorinated contaminants (TCE, TCA, perchloroethylene) in drinking water

Chaired an expert panel review of EPA's inhalation toxicity criteria for 1,2-dichloroethane and 1,1,2-trichloroethane

Conducted and published a probabilistic analysis of household exposure to TCE and perchloroethylene in tapwater to demonstrate the health protectiveness of the EPA's MCLs

Specific Experience with Pharmaceuticals, Medical Devices, and Consumer Products

Currently serving as an expert witness in exposure assessment, industrial hygiene, and toxicology in cases involving popcorn worker exposure to diacetyl and artificial butter

Evaluated the metabolic and toxicity results (from animal and clinical data) of Levaquin and Ofloxacin to determine whether and to what degree the two drugs confer a different therapeutic index

Consulted in personal injury lawsuits involving healthcare worker use of latex gloves and associated claims of dermal sensitization

Prepared an expert report regarding likelihood of association between use of rug cleaner and plaintiff's alleged symptoms of RADS

Prepared a report and manuscript describing the possible health risks associated with exposure to rubber tire particles in the environment

Served as an expert exposure and risk assessment expert in a case involving formaldehyde emissions from kitchen cabinets

Deposed in a case involving claims of health harm associated with exposure to airbag contents (azide and talc) following airbag deployment and failure

Conducted an analysis of health risks associated with exposure to lead in detailing paint that contained up to 30% lead

Specific Experience with Warnings, Labels, and State-of-the-Art Analyses

Served as a state-of-the-art expert in warnings and labels in cases involving worker exposure to “draw fluids” during automobile manufacture

Assessed whether the manufacture of a petroleum solvent “had knowledge” that the use of the solvent might be associated with exposure to significant levels of benzene

Assisted counsel in determining whether labels and warnings on a lead-containing paint were adequate and appropriate under Proposition 65

Serving as a state-of-the-art expert in warnings and labels in cases involving worker exposure to asbestos during brake servicing

Specific Experience with Stack Emissions

Prepared a multi-pathway exposure and risk assessment for the U.S. Army chemical weapons incinerator in Tooele, Utah. The purpose of the analysis was to assess the merits of an injunction filed by a plaintiff’s consortium that operation of the incinerator would pose a risk to surrounding residents. Testified twice in court, on behalf of the Department of Justice. The judge’s decision to permit the incinerator to operate was based in part on Dr. Finley’s findings and testimony.

Served as an expert exposure and risk assessment expert in a case involving community exposures to particulate emissions from a steel-manufacturing facility

Prepared a multi-pathway assessment of the health risks associated with emissions of dioxin particulates and vapors from a combustion source. The State of California had previously determined that the dioxin risks were significant and that the client would have to warn the surrounding residential community. Used refined risk assessment techniques to demonstrate that the potential health risks were insignificant. Exposure pathways considered included ingestion of mother’s milk, vegetable crops, and local meat and dairy products.

Prepared a multi-pathway exposure and risk assessment for a state Superfund site in Illinois. The assessment demonstrated that particulate emissions from a client’s insecticide-formulating facility did not pose a significant health risk to the surrounding community. Accordingly, the Illinois EPA issued a no-action alternative for the site, and no remediation was required.

Specific Experience with Dioxins and PCBs

Expert witness in a case concerning alleged “recreational” exposures to Aroclor 1254 in soil at a former capacitor manufacturing site

Involved in research with EPA and WHO scientists to refine the current TEF scheme for dioxin and PCB risk assessment.

Conducted (and published) a human exposure study designed to assess the degree to which naturally occurring dietary compounds (“endodioxins”) contribute to the overall TEQ dose in the general population

Conducted (and published) the first soil bioavailability study to examine all 17 2,3,7,8-substituted PCDD/Fs

Evaluated dioxin levels in the blood of workers employed at magnesium facility in Utah

Served as principal-in-charge of a Superfund project involving dioxin- and PCB-contaminated sediments in a major waterway in New Jersey. This project involves the use of fingerprinting techniques for source identification, food-web modeling, and defense against natural resource damage claims. Dr. Finley has published over 25 papers regarding the proper use of exposure and risk assessment techniques for this site.

Designed the first sediment toxicity study conducted to demonstrate that dioxin poses no risk to benthic invertebrates.

Assisted in the development, conduct and interpretation of a year-long creel-angler survey designed to accurately estimate the fish and crab consumption rates (and associated risks) in a PCB-contaminated waterway

Conducted (and published) an analysis of human and ecological risks associated with suspension of dioxin-contaminated sediments as a result of dredging

Invited to speak at an EPA external peer-review workshop for the guidance document PCBs: Cancer Dose Response Assessment and Application to Environmental Mixtures.

Evaluated PCB-related risks to anglers consuming fish from the Fox River, Wisconsin

Specific Experience with Chromium

Designed and conducted the first human sweat extraction study for the purposes of measuring bioavailability of chromium from soil

Organized and chaired an expert panel investigation into the technical merits of New Jersey Department of Health’s urinalysis and house dust analysis of residents living near chromium-impacted areas

Served as principal-in-charge of an industry-funded investigation into OSHA's basis for lowering the permissible exposure limit for chromium (VI)

Served as an expert exposure and risk assessment witness in a toxic tort case involving residential exposure to chromium emissions from a former plating facility in Southern California

Managed a complex assessment of the health risks associated with chromium-contaminated soil at more than 100 sites in New Jersey. This assessment entailed the development of new sampling and analytical techniques for ambient chromium concentrations, design and implementation of several human exposure studies, and extensive regulatory negotiations with the New Jersey Department of Environmental Protection.

Conducted a \$2M human patch-testing study for the purposes of identifying the dermatitis elicitation threshold for chromium. This study was used to demonstrate that the Agency's initial position on dermatitis-based cleanup standards was seriously flawed.

Invited to speak at an EPA Workgroup session on chromium reference doses regarding proposed methods for setting a chromium (III) reference dose

Prepared and submitted comments to EPA's proposed inhalation "reference concentrations" for chromium. As a result of the submitted comments, EPA withdrew the proposed values. Invited to serve on an EPA work group to evaluate better methods for setting these criteria.

Specific Experience with Pathogens

Designed a sampling analysis program for combined sewer overflows (CSOs) in the Passaic River. The purpose of the program is to conduct a pathogen risk assessment for recreationists who come in contact with the surface water of the River. Several samples have been collected during storm events and the bacterial/viral content of the samples is currently being interpreted to develop estimates of increased risk of various diseases.

Interpreted pathogen content of tapwater samples following plaintiff's assertion that ingestion had caused an array of autoimmune diseases.

Deposed as an exposure and risk assessment expert in EPA et al v. City of Los Angeles. The EPA alleged that uncontrolled sewage spills had impacted Santa Monica Bay to such a degree that beach recreators were at great risk of developing pathogen-related diseases. Dr. Finley reviewed the monitoring data and developed a pathogen exposure and risk analysis.

Specific Experience with Creosote, PAHs, Coal Tar, and Wood-treating Sites

Deposed as an expert exposure and risk assessment witness in a federal case involving creosote and pentachlorophenol production at a former wood-treating site in St. Louis

Currently serving as an exposure and risk assessment expert in a case involving community allegations of health effects from historical exposures to emissions from a wood-treating facility in Louisiana

Served on an expert panel that evaluated the health risks associated with creosote and coal tar-containing products; the panel concluded that the toxicology and epidemiology data do not support a conclusion that these substances are carcinogenic in humans

On behalf of a creosote manufacturer, helped determine “background” levels of PAH exposure in a community (from diet, etc.) vs. PAH exposures associated with trace creosote levels in residential soils

Conducted over 50 environmental risk assessments (RCRA, CERCLA, RBCA, etc.) in which PAHs in soils were the primary contributor to potential human health risk; a majority of these involved derivation of site-specific soil standards using state-of-the-art exposure assessment techniques. Approximately half of these projects involved regulatory interaction.

Specific Experience with Industrial Slags

Served as principal-in-charge of a risk assessment involving residential exposure to arsenic-containing industrial slag

Designed and conducted a human exposure study (involving the direct ingestion of soil) for the purposes of assessing the disposition of a priority pollutant metal in an industrial slag

Served as principal-in-charge of an ongoing evaluation of the public health risk associated with numerous beneficial uses of steel slag

Other Projects

Evaluated risks associated with ingestion of fish and shellfish from San Diego Harbor

Demonstrated that post-remedial concentrations of mercury in soil at an industrial site in Puerto Rico did not pose a significant health risk to individuals working on the property. EPA Region II then formally closed the site with no further remediation required.

Prepared an avian health risk assessment at a state Superfund site. The assessment, involved collection and analysis of live and dead birds for cyclodiene content.

Managed two ecological impact studies in Melbourne, Australia

Served as principal-in-charge of four separate RCRA risk assessments involving more than 400 solid waste management units

On behalf of a former toxaphene manufacturer, conducted an analysis of toxaphene-related risks to humans consuming fish in a waterway in Georgia

Publications

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Presentations and Published Abstracts

Finley, B.L., L.L.F. Scott and D.A. Galbraith. Pleural mesothelioma in U.S. auto mechanics: Expected vs. reported cases from 1975-2007. Presented at the 2010 Society for Risk Analysis Conference. December 5-8, 2010. Salt Lake City, UT.

Phelka, A.D. and B.L. Finley. Potential health hazards associated with exposures to asbestos-containing drywall accessory products: A state-of-the-science assessment. Presented at the 2010 Society for Risk Analysis Conference. December 5-8, 2010. Salt Lake City, UT.

Hollins, D.M., D.A. Galbraith, and B.L. Finley. Occupational exposure to diacetyl and potential health effects: A weight of evidence analysis. Poster presentation at the 2010 Society for Risk Analysis Conference. Poster #47. December 5-8, 2010. Salt Lake City, UT.

Shay, E., K. Thuett, and B. Finley. Atrazine in Drinking water: Comparison of measured and estimated peak concentration vs. acute health benchmarks. Poster presentation at the 2010 Society for Risk Analysis Conference. Poster #49. December 5-8, 2010. Salt Lake City, UT.

Marwood C., B.L. McAtee, M.L. Kreider, R. Ogle, B.L. Finley, and J.M. Panko. Identification of Toxic Constituents in Tire and Road Wear Particle Extracts. Poster presentation at the 2010 Society of Environmental Toxicology and Chemistry (SETAC) Conference. November 7-11, 2010. Portland, OR.

Marwood C, B.L. McAtee, M.L. Kreider, B.L. Finley, J.M. Panko. Chronic Toxicity of Tire/Road Wear Particles in Sediment to Aquatic Organisms. Poster presentation at the 2010 Society of Environmental Toxicology and Chemistry (SETAC) Conference. November 7-11, 2010. Portland, OR.

Fillos, D.J., W.J. Luksemburg, M. Anderle de Saylor, L.L.F. Scott, and B.L. Finley. Measurements of PCDD and PCDF Concentrations in Wild-Caught and Farm-Raised Shrimp From The U.S. Retail Market. Poster presentation at the 30th International Symposium on Halogenated Persistent Organic Pollutants. Abstract #1498, Poster Board #59. September 12-17, 2010. San Antonio, TX.

Fillos, D.J., W.J. Luksemburg, and B.L. Finley. TEQ Calculations and Daily Intake Estimates Associated With PCBs in Shrimp From The U.S. Retail Market. Poster presentation at the 30th International Symposium on Halogenated Persistent Organic Pollutants. Abstract #1624, Poster Board #609. September 12-17, 2010. San Antonio, TX.

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Donovan, B., E.P. Donovan, S.H. Gaffney, P. Scott, and B.L. Finley. 2010. Human Health Risks Associated with Fish and Shellfish Consumption in an Industrial Leasehold in a Southern California Bay. Poster presentation at the Society of Toxicology's Annual Meeting #2315PB646. March 7-11, 2010. Salt Lake City, UT.

Scott, L.F., J. Keenan, B.L. Finley, and S.H. Gaffney. 2009. Using Blood Measurements to Assess Exposure to Dioxin/Furans: Potential Influence of Elevated Detection Limits. Presented

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Finley, B.L. A Screening Level Evaluation Of Noncancer Hazards For Occupational Exposures To Decachlorobiphenyl From Indoor Dust. Poster presentation at the 28th International Symposium on Halogenated Persistent Organic Pollutants (POPs) – Dioxin Conference. #321. August 17-22, 2008. Birmingham, England, U.K.

Finley, B.L. Site-Specific Dermal Risk Assessment For Industrial Workers. Poster presentation at the 28th International Symposium on Halogenated Persistent Organic Pollutants (POPs) – Dioxin Conference. #305. August 17-22, 2008. Birmingham, England, U.K.

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Haws, L.C., M.J. DeVito, J.N. Walker, L.S. Birnbaum, K.M. Unice, P. Scott, M.A. Harris, J.A. Tachovsky, W.H. Farland, B. Finley, and D.F. Staskal. 2008. Development of weighted distributions of REPs for dioxin-like compounds: implications for risk assessment. Abstract # 1178. Presented at Society of Toxicology's 47th Annual Meeting, March 16-20, 2008. Seattle, WA.

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Staskal, D.E., E.P. Donovan, K.M. Unice, L.C. Haws, J. Roberts, B. Finley, and M. Harris. Human health risks associated with exposure to pathogens in waters and sediments of the lower Passaic River. Abstract # 1800. Presented at Society of Toxicology's 47th Annual Meeting, March 16-20, 2008. Seattle, WA.

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Haws, L.C., L.L.F. Scott, D.F. Staskal, M.A. Harris, and B.L. Finley. 2007. Dioxin-like compounds in workers at a primary magnesium production facility. Abstract # P261. Presented at Dioxin 2007. September 2-7, 2007. Tokyo, Japan.

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Haws, L., N. Walker, M. DeVito, L. Birnbaum, K. Unice, P. Scott, M. Harris, W. Farland, B. Finley, and D. Staskal. 2007. Development of Weighted Distributions of Reqs for Dioxin-Like Compounds (DLCs). Abstract # 1560. Presented at Society of Toxicology's 46th Annual Meeting, March 25-29, 2007. Charlotte, NC.

Morinello, E.J., J.M. Warmerdam, and B.L. Finley. 2007. Absolute oral bioavailability of polychlorinated dibenzo-p-dioxins/dibenzofurans in soil. Abstract # 825-302. Presented at Society of Toxicology's 46th Annual Meeting. March 25-29, 2007. Charlotte, NC.

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Pierce, J., J. Warmerdam, and B. Finley. 2007. Estimating health risks in workers aboard crude oil tankers due to exposure to n-hexane, toluene, and benzene. Abstract # 1999-218. Presented at Society of Toxicology's 46th Annual Meeting. March 25-29, 2007. Charlotte, NC.

Roberts, J., D.A. Galbraith, and B.L. Finley. 2007. A comprehensive review of occupational exposure to diacetyl in microwave popcorn facilities. Abstract # 2000-219. Presented at Society of Toxicology's 46th Annual Meeting. March 25-29, 2007. Charlotte, NC.

Staskal, D., E. Donovan, J. Roberts, K. Unice, B. Finley, and M. Harris. 2007. Human health risk associated with exposure to pathogen-contaminated sediments. Abstract # 1618-120. Presented at Society of Toxicology's 46th Annual Meeting. March 25-29, 2007. Charlotte, NC.

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Harris, M.A., and B. Finley. 2005. The TCDD TEQ in Human Blood From Dietary vs. Anthropogenic Dioxins: A Dietary Study. Abstract #392. Presented at Society of Toxicology's 44th Annual Meeting. March 6-10. New Orleans, LA.

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Jersey harbor. Presented at Proceedings of International Conference on Remediation of Contaminated Sediments. October 10-12, 2002. Venice, Italy.

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Proctor, D.M., B.L. Finley, and D.J. Paustenbach. 2001. Is Hexavalent Chromium Carcinogenic Via The Oral Route of Exposure An Evaluation of the State of the Science and Implications for Drinking Water Regulations. Abstract # 1499. Presented at Society of Toxicology's 40th Annual Meeting. March 25-29. San Francisco, CA.

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Finley, B.L., D.J. Cher, and S.M. Hays. 2000. Natural Rubber Latex Allergy: A Critical Review. Abstract # 1160. Presented at Society of Toxicology's 39th Annual Meeting. March 19-23. Philadelphia, PA.

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Chute, S.M., S.K. Overman, B.D. Kerger, B.L. Finley, and D.J. Paustenbach. 1996. The Chromium(VI) Reductive Capacity of Household Beverages: Implications for Risk Assessment.

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Clark, J.J.J., G.E. Corbett, B.D. Kerger, B.L. Finley, and D.J. Paustenbach. 1996. Dermal Uptake of Hexavalent Chromium in Human Volunteers: Measures of Systematic Uptake from Immersion in Water at 22 ppm. Abstract # 74. Presented at Society of Toxicology's 35th Annual Meeting. March 10-14. Anaheim, CA.

Corbett, G.C., E. O'Flaherty, B.D. Kerger, B.L. Finley, and D.J. Paustenbach. 1996. Reduction Kinetics of Hexavalent Chromium in Human Blood. Abstract #77. Presented at Society of Toxicology's 35th Annual Meeting. March 10-14. Anaheim, CA.

Dodge, D.G., J.J.J. Clark, B.D. Kerger, R.O. Richter, B.L. Finley, and D.J. Paustenbach. 1996. Assessment of Airborne Hexavalent Chromium in the Home Following Use of Contaminated Tapwater. Abstract #600. Presented at Society of Toxicology's 35th Annual Meeting. March 10-14. Anaheim, CA.

Finley, B.L., B.D. Kerger, G.C. Corbett, and D.J. Paustenbach. Pharmacokinetics of Drinking Water Exposure to Selected Chromium (III and VI) Compounds in Human Volunteers. Abstract #73. Presented at Society of Toxicology's 35th Annual Meeting. March 10-14. Anaheim, CA.

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Paustenbach, D.J., S.M. Hays, B.D. Kerger, and B.L. Finley. 1996. An Analysis of Interindividual Variability in Uptake and Elimination of Chromium from Human Volunteers. Abstract #180. Presented at Society of Toxicology's 35th Annual Meeting. March 10-14. Anaheim, CA.

Finley, B.L., R.L. Norton, and M.L. Gargas. 1995. Urinary chromium concentrations in humans following ingestion of safe doses of hexavalent and trivalent chromium: implications for biomonitoring. *The Toxicologist* 15:1036. Presented at the 34th Annual Meeting of the Society of Toxicology. Baltimore, MD.

Kerger, B.D., B.L. Finley, and D.J. Paustenbach. 1995. Cost-Benefit Analysis of California Policy on Cancer Risk: A Case Study on Chromium (VI). Abstract #203. Presented at Society of Toxicology's 34th Annual Meeting. March 5-9. Baltimore, MD.

Gargas, M.L., B.L. Finley, R.L. Norton, D.M. Proctor, and D. J. Paustenbach. 1994. Biomonitoring of chromium (Cr) exposure by urinary excretion: bioavailability and sampling design. *The Toxicologist* 14:383. Presented at the 1994 Society of Toxicology Meeting. Dallas, TX.

Gargas, M.L., P.K. Scott, B.L. Finley, and R.H. Reitz. 1994. Refinements in the exposure assessment process. Presented at the Conference on Temporal Aspects in Risk Assessment for Non-Cancer Endpoints. April 18-20, 1994. Wright-Patterson AFB, OH.

Malsch, P.A., D.M. Proctor, and B.L. Finley. 1994. Estimation of chromium inhalation RfC by the benchmark dose method. Presented at the Society of Toxicology 33rd Annual Meeting.

Finley, B.L., D.M. Proctor, and D.J. Paustenbach. 1993. An alternative to the USEPA's proposed inhalation reference concentrations for hexavalent chromium. Abstract #1643. Presented at 32nd Annual Meeting of the Society of Toxicology, New Orleans, LA.

Gargas, M.L., M.A. Bono, P.K. Scott, B.L. Finley, and D.J. Paustenbach. 1993. Approaches to assessing human exposure to soil contaminants at wood preserving facilities. *The Toxicologist* 13:1045. Presented at the 32nd Annual Meeting of the Society of Toxicology. March 14-18, 1993. New Orleans, LA.

Proctor, D.M. and B.L. Finley. 1993. A methodology for setting soil cleanup goals based on protection of allergic contact dermatitis. Presented at the Society for Risk Analysis Annual Meeting. December 5-8, 1993.

Finley, B.L., M. Harris, and D.J. Paustenbach. 1991. Recent changes in regulatory toxicity rankings for wood-treating chemicals and their impact on risk assessment and remediation at wood-treating sites. Presented at the American Wood Preservers Institute. Scottsdale, AZ.

Harris, M.A., B.L. Finley, R.J. Wenning, and D.J. Paustenbach. 1991. Evaluation of Potential Sources of 1,2,8,9-TCDD in Aquatic Biota from Newark Bay. Abstract #729. Presented at Society of Toxicology's 30th Annual Meeting.

Wenning, R.J., M.A. Harris, M.J. Unga, B.L. Finley, and D.J. Paustenbach. 1991. PCDD and PCDF fingerprint patterns in surficial sediments from the lower Passaic River and Newark Bay using multivariate statistics. Abstract #446. Presented at 12th Annual Meeting of Society of Environmental Toxicology and Chemistry. November 3-7, 1991. Seattle, WA.

Finley, B.L., R.J. Wenning, M.J. Unga, S. Huntley, and D.J. Paustenbach. 1990. PCDDs and PCDFs in surficial sediments from the lower Passaic River and Newark Bay. pp. 409-414. In: Proc. Presented at 10th International Symposium on Chlorinated Dioxin and Related Compounds.

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Annual Meeting of the Society of Environmental Toxicology and Chemistry. November 11-15, 1990. Washington, DC.

Finley, B.L., and B.D. Hammock. 1987. Introduction of Microsomal Cholesterol Epoxide Hydrolase by Clofibrate. Abstract #86. Presented at Society of Toxicology's 26th Annual Meeting.

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