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*Testimony before the California Regional
Quality Control Board in the San Diego Bay
Shipyard Sediment Site Matter*

Qualifications

- B.S. Biological Sciences, Cornell University
- Ph.D. Pharmacology/Toxicology, Washington State University
- Board-certified in toxicology
- 20 years health risk assessment experience
 - Published over 25 papers on health risk assessment, including several that address fish consumption and sediment contamination

Human Health Exposure Factor Estimates Based Upon A Creel/Angler Survey of the Lower Passaic River (Part 3)

Rose Ray

Exponent, Menlo Park, California, USA

Valerie Craven

Exponent, Santa Rosa, California, USA

Matthew Bingham and Jason Kinnell

Veritas Economic Consulting, Cary, North Carolina, USA

Elizabeth Hastings

Knowledge Networks, Needham Heights, Massachusetts, USA

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Recommended Distributions for Exposure Factors Frequently Used in Health Risk Assessment

**Brent Finley,^{1,2} Deborah Proctor,^{1,3} Paul Scott,^{1,3} Natalie Harrington,^{1,4}
Dennis Paustenbach,^{1,2} and Paul Price^{1,4}**

PRELIMINARY ASSESSMENT OF PCB RISKS TO HUMAN AND ECOLOGICAL HEALTH IN THE LOWER PASSAIC RIVER

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Evaluation of Three Measures of Exposure Concentration: A Case Study of Surface Sediment Concentrations in the Passaic River

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What is a human health risk assessment?

- An analysis of chemical exposure and potential health hazard from eating fish and shellfish at the NASSCO leasehold:
 - which chemicals are in the fish?
 - what are the fish tissue concentrations?
 - how much fish do people eat?
 - will eating the fish pose a health risk?

Overview of Opinions

1. The DTR is not a human health risk assessment; it is a simplistic *screening analysis* that does not accurately describe potential risks at NASSCO.
2. Chemical concentrations in fish in the NASSCO leasehold are actually no different from local “background.”
3. The DTR’s exposure assumptions were unrealistic, leading to risk estimates that are implausible.
4. Using realistic (yet conservative) exposure assumptions, I find that risks from consumption of fish and shellfish caught in the NASSCO leasehold are well below levels of concern.

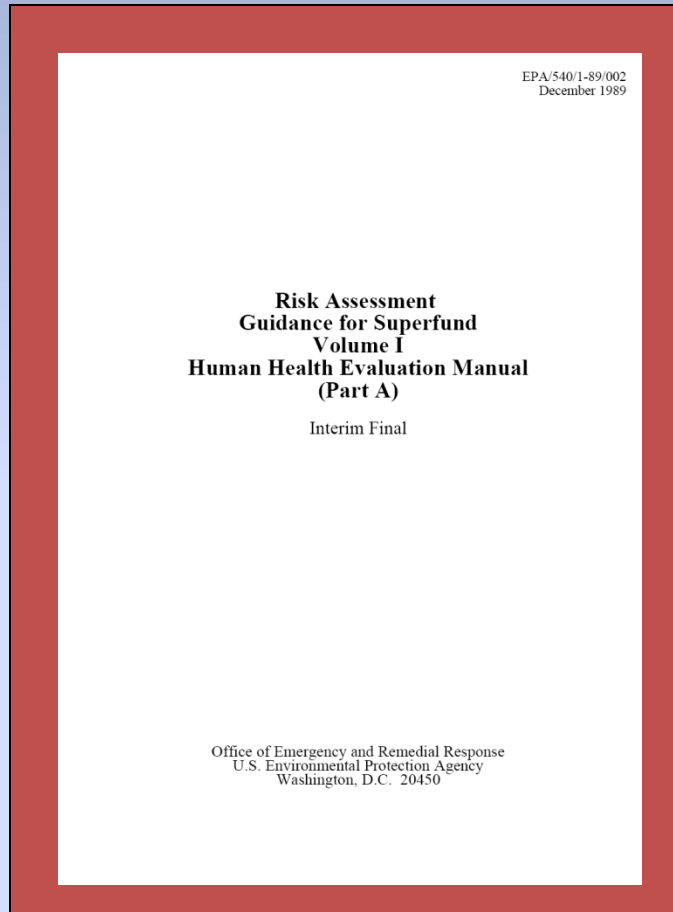
Opinion #1

The DTR is not a human health risk assessment; instead, it is a *screening analysis*. Therefore it is not an accurate representation of potential risks at NASSCO.

The role of a screening analysis

- Used to determine if a health risk assessment is even *necessary*
- Does the site pose a risk under implausible, “worst-case” conditions?
 - If no, then usually no further action required
 - If yes, then a risk assessment is conducted
- Screening analyses are NOT intended to be used in making remedial decisions

U.S. EPA (1989)

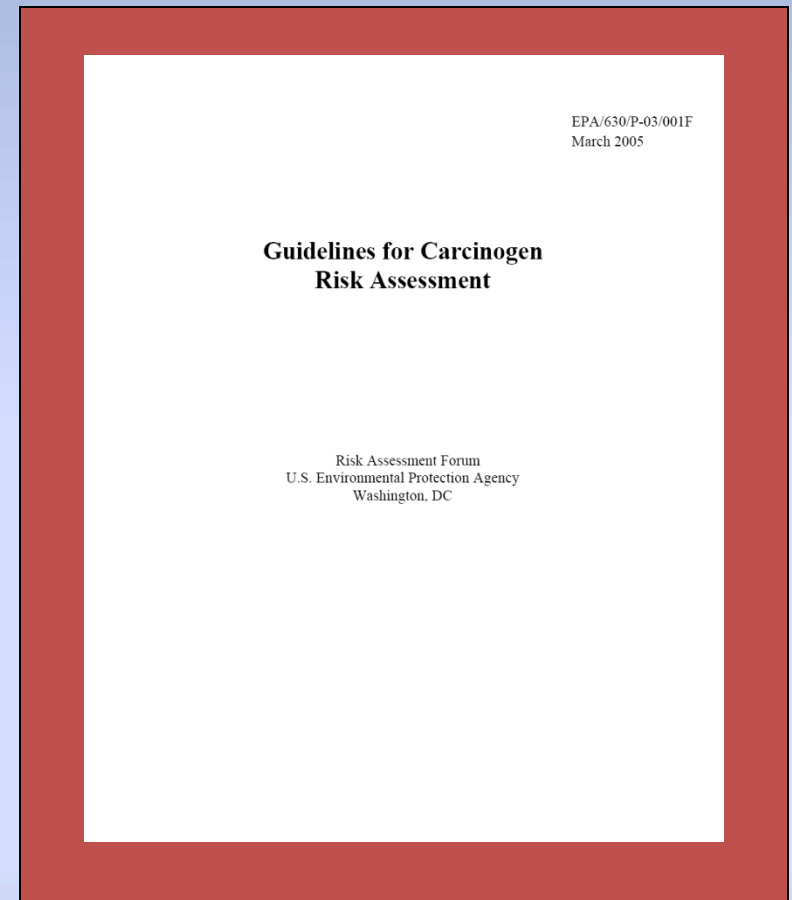


- “...it is important to remember that if a *screening level* approach suggests a potential health concern, *the estimates of exposure should be modified to reflect more probable exposure conditions*”

USEPA (1989b). Risk Assessment Guidance for Superfund. Volume I. Human Health Evaluation Manual (Part A). Interim Final U.S. Environmental Protection Agency. Washington, D.C. December 1989. EPA/540/1-89/002 (p. 6-25).

U.S. EPA (2005)

“Screening-level assessments may...readily use...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*”



USEPA (2005). Guidelines for carcinogen risk assessment. U.S. Environmental Protection Agency. Washington, D.C. March 2005. EPA/630/P-03/001F. Pgs. 1-9 – 1-10.

Why the DTR is a screening analysis

- The DTR contains several unreasonable assumptions:
 - Assumed that a person trespassed onto the NASSCO property and ate several fish EVERY DAY for 30 years!
 - Assumed that the NASSCO property was the only source of fish in the diet
 - For “subsistence” anglers, assumed the entire fish was eaten, *every fish meal*
- ...as a result, the risk estimates in the DTR are not realistic

Opinion #2

Contaminant concentrations in fish in the NASSCO leasehold are actually no different than at local “background” reference locations

Comparison of NASSCO and reference locations

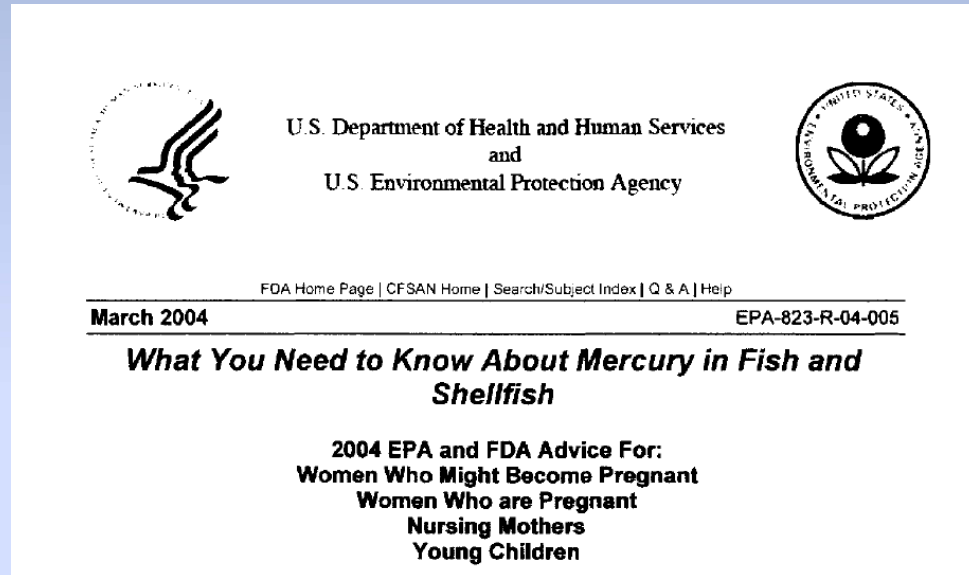
- Three locations of interest:
 - Inside NASSCO leasehold
 - Outside NASSCO leasehold
 - Reference location (selected by RWQCB staff)
- Statistical comparisons indicated **NO DIFFERENCE** in fish tissue concentrations between any of these locations

Fish tissue PCB concentrations

- NASSCO PCB concentrations were similar to or lower than those measured elsewhere in San Diego and California
 - County of San Diego Health Risk Study (1990) found no difference in PCB tissue concentrations by location
- PCB concentrations in fish collected from inside NASSCO leasehold are lower than FDA's action level of 2 ppm

Fish tissue mercury concentrations

- Average mercury concentrations in fish in NASSCO leasehold (0.12 ppm) consistent with tissue concentrations classified by EPA as “lower” levels of mercury
- Same as average concentration found in canned, light tuna



SPECIES	MERCURY CONCENTRATION (PPM)				NO. OF SAMPLES	SOURCE OF DATA
	MEAN	MEDIAN	MIN	MAX		
TUNA (Canned, Light)	0.12	0.08	ND	0.85	131	FDA SURVEY 1990-03

Opinion #3

- The DTR exposure assumptions were overly conservative and unrealistic.
 - Consumption of *entire fish, every fish meal*, for subsistence anglers
 - Use of *maximum* tissue concentrations only
 - *Entire* fish diet comes from NASSCO
 - *Daily* access to the site for *30 years*
 - Use of fish consumption rates from *Santa Monica Bay*
 - Assumed the presence of inorganic arsenic

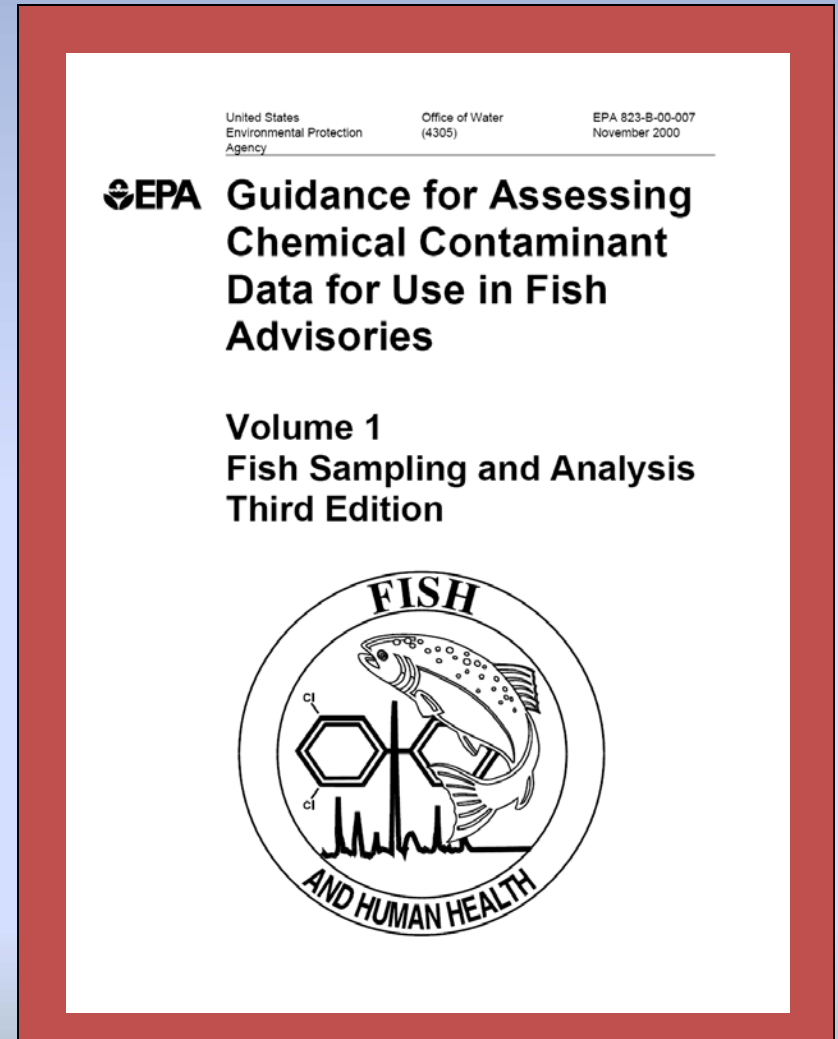
No basis for assumption that subsistence anglers would eat entire fish or shellfish

- None of the EPA risk assessment guidance documents recommend the use of whole fish/shellfish concentrations
- No basis for assumption that subsistence anglers would eat *entire fish, every fish meal*
- Fillet measurements are more realistic
- The DTR should have used the NASSCO fillet data



EPA (2000)

- The EPA specifically recommends the use of edible tissue data in screening analyses
- “....skin-on filets...and *edible portions* of shellfish are recommended for ...*screening studies* to provide *conservative estimates* of typical exposures...”

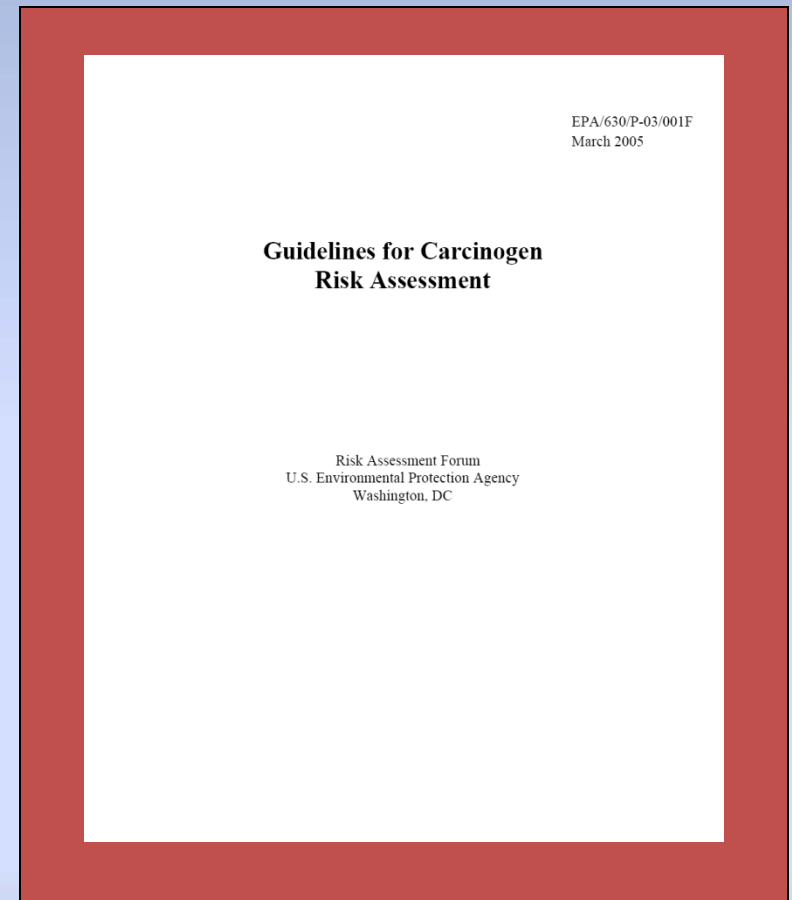


Inappropriate use of maximum tissue concentrations

- The DTR used maximum tissue concentrations *only*
- EPA risk assessment guidance documents call for the use of averages and “upper-bounds” (95th percentile)
- Risk estimates based on average and upper bound tissue concentrations should have been included.

U.S. EPA (2005)

“Screening-level assessments may... readily use...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*”



USEPA (2005). Guidelines for carcinogen risk assessment. U.S. Environmental Protection Agency. Washington, D.C. March 2005. EPA/630/P-03/001F. Pgs. 1-9 – 1-10.

Implausible fish consumption rates

- EPA risk assessment guidance emphasizes the importance of using *site-specific information*
- Fish consumption rates from recreational areas are not applicable to NASSCO
- The DTR should have used fish consumption rates from industrialized settings



Santa Monica Bay¹



NASSCO leasehold²

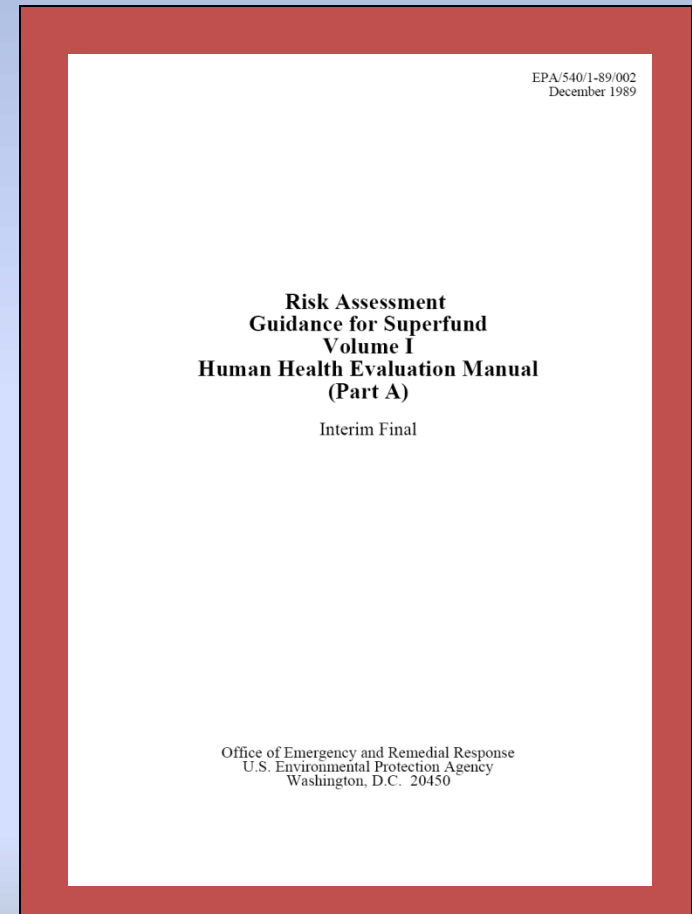
Fishing does not occur at the NASSCO leasehold

- There is no public access
- Significant security measures and 24-hr surveillance are in place at the facility, from both land and water access points
- Based on the Port Master Plan, it is designated an industrial area, with a lease that will last until at least 2040



30-year exposure duration

- How many years would a person come to NASSCO to fish?
- The DTR used the maximum EPA “default” estimate of 30 years
- The DTR should have considered the EPA’s central tendency estimate of 9 years

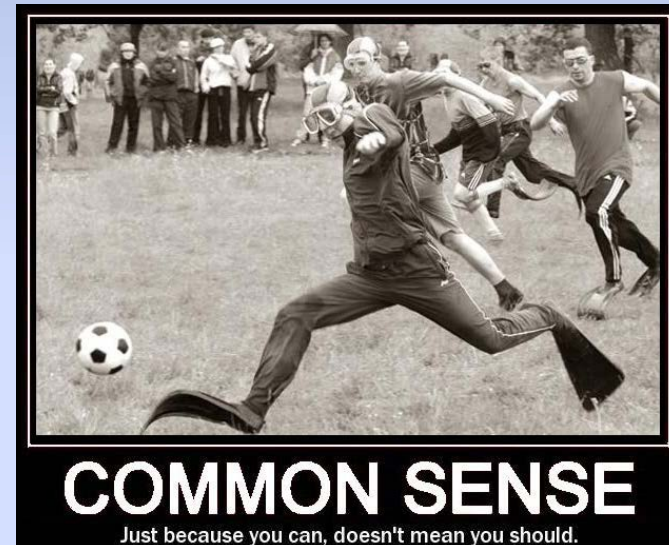


4% inorganic arsenic assumption is not realistic

- The primary form of arsenic found in fish and shellfish is **organic**, which is non-toxic
- Fish often don't contain measurable **inorganic** arsenic
- None of the NASSCO fish were analyzed for inorganic arsenic
- Yet the DTR assumed that 4% of the arsenic in the NASSCO fish was inorganic; most fish contain far less than this
- The arsenic risk could very well be zero

What is the impact of the DTR assumptions?

- Repeated use of implausible values for every exposure factor has resulted in risks that are over-estimated by at least several orders of magnitude
- In reality, the plausible risks are far lower



Changing even one of DTR's assumptions results in significantly lower risk estimates

DTR's arsenic risk
 6.12×10^{-6}

DTR's risk threshold
(1 in 1,000,000)



1.22×10^{-7}

4.2×10^{-8}



Change fish consumption rate to industrial



Use average tissue concentration, not maximum

Opinion #4

- Using more realistic (yet still conservative) exposure assumptions, the potential risks associated with fish consumption at NASSCO leasehold are well below levels of regulatory concern.
 - Refined assumptions to reflect industrial nature of site
 - Adjusted other assumptions to be more consistent with EPA risk assessment guidance

Calculating Exposure

- Exposure is the daily amount of chemical consumed from eating fish (mg/kg-day)

$$\begin{array}{ccccccccc} \text{Tissue} & & \text{Fish} & & \text{Fraction fish} & & \text{Exposure} & & \text{Exposure} \\ \text{chemical} & & \text{consumption} & & \text{ingested from} & & \text{duration} & & \text{frequency} \\ \text{concentration} & \times & \text{rate} & \times & \text{site} & \times & \text{(years)} & \times & \text{(days/year)} \\ \text{(mg/kg-wet weight)} & & \text{(kg/day)} & & & & & & \\ \hline & & \text{Body weight} & \times & \text{Averaging} & \times & \text{Conversion} & & \\ & & \text{(kg)} & & \text{time} & & \text{factor} & & \\ & & & & \text{(days)} & & \text{(1000 } \mu\text{g/mg)} & & \end{array}$$

Specific changes in my risk assessment

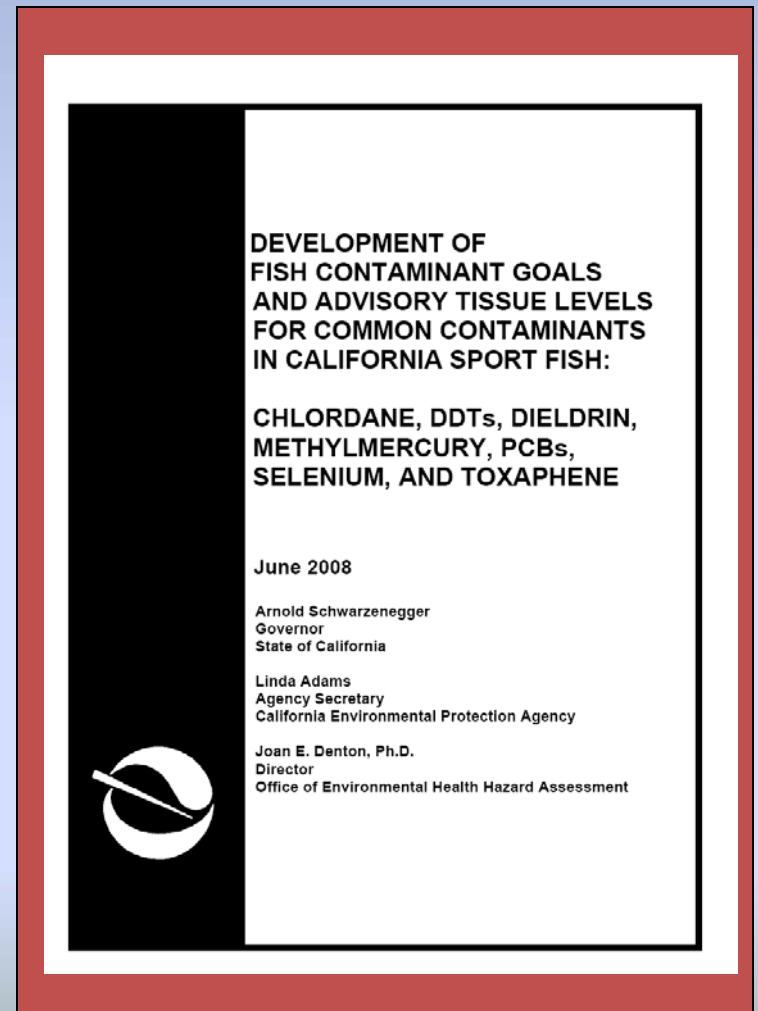
Assumption from DTR	Is this assumption realistic?
Used maximum tissue concentrations	NO. I used average and upper bound concentrations
Used fish consumption rate from Santa Monica Bay	NO. I used fish consumption rate from industrial area
Assumed subsistence angler would consume whole fish, guts and all	NO. I used edible tissue concentrations, as suggested by EPA
Assumed exposure duration of 30 years	NO. I used average exposure duration recommended by EPA, 9 years
Assumed 4% arsenic was inorganic	NO. I used a range of 0-4%

Using more realistic assumptions, risk estimates are well below levels of regulatory concern

- All risks are below the 1 in 100,000 benchmark as defined by CAL EPA
- All PCB risks are below the OEHHA benchmark of 1 in 10,000 set specifically for fish consumption
- Not surprising, given the fact that the tissue contaminant levels are no greater than “background” reference locations

California's level of acceptable risk for fish

“OEHHA considers that a maximum risk level of 1 in 10,000 appropriately balances the cancer risk associated with fish consumption with the numerous known health benefits that can be accrued from eating fish.” (OEHHA, 2008, p. 55)



Summary of my opinions

- The DTR is not a proper health risk assessment; it is a screening analysis that far over-states the risks
- The assumptions used by in the DTR are contrary to the fact that people do not fish at NASSCO, and probably never will
- Use of more realistic (yet still conservative) exposure assumptions yields risk estimates that are below levels of regulatory concern

Conclusions

- Refine just a few of the exposure assumptions in the DTR to more realistic values
- No significant impairment of beneficial uses with respect to human health