ARCADIS Design & Consultancy for natural and built assets

PERSPECTIVES ABOUT ACCEPTABLE RISK:

Who are we protecting and did we mean to?

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Themes Today

- Introduction and background
- Why focus on target risk
- Origin of $1x10^{-6}$
- Some allowable risk levels: is $1x10^{-6}$ magical?
- Perspectives about target risk: various causes of death
- How protective is $1x10^{-6}$ when used to derive HHWQC?
- Improving public health decision making

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Introduction and Background

- Journey of several decades in assisting states develop human health water quality criteria (HHWQC)
- Catalyzed by the results of probabilistic risk assessments (PRA) that we and others have conducted in the past couple of years
  - To whom (which percentile(s) of the population) should different allowable risk levels apply?
  - Little guidance exists on how to interpret the range of risks estimated PRA
- The questions raised about target risk apply to all risk assessments, not just PRA
- How protective are commonly used target risks? Over-protective? Under-protective? Just right?
- This is a recap of some of the highlights of that journey to date

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Why Focus on Target Risk?

- $$HHWQC = \frac{TR \times BW}{\left(DI + \left(FCR \times BAF\right)\right) \times CSF}$$
- We have spent substantial resources refining several of these inputs
- Their effect on HHWQC is often limited
  - Typical changes are in the percents or a few-fold
  - Translate to “only” similar change in HHWQC
- Target risk is different
  - Can result in a 10-fold change in HHWQC
  - Not necessarily true for PRA-based HHWQC

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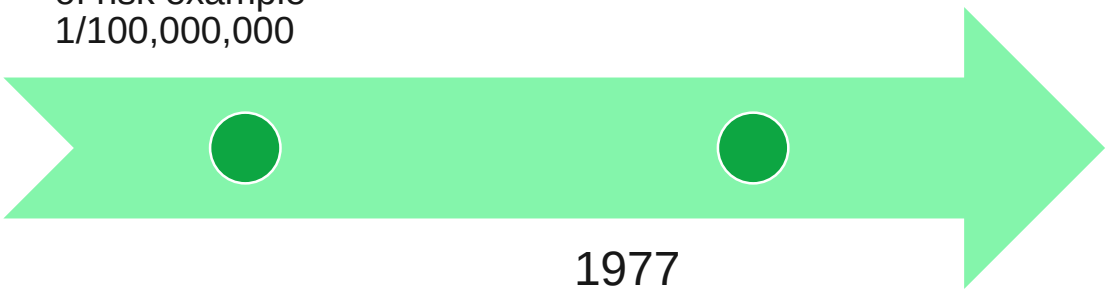
Origin of $1x10^{-6}$

1973

- FDA: minimal probability of risk example 1/100,000,000



1977

- FDA: benchmark for experimental risk 1/1,000,000

No detailed publically available analysis is available that documents $1x10^{-6}$ as the more appropriate acceptable risk level to use when setting criteria, clean-up levels and other human health risk-based benchmarks (rather than $1x10^{-5}$, $1x10^{-7}$, $1x10^{-4}$, etc.).

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$1x10^{-6}$ is Not Magical: Benchmarks for "Acceptable" Risk

U.S. Law / Regulation	Focus	Risk Standard	Criterion for Carcinogens
Clean Water Act	Surface water	Adverse health impacts	$1x10^{-5}$ to $1x10^{-7}$
Safe Drinking Water Act	Public drinking water	Any adverse effect	Goal: 0 Enforceable standard: $1x10^{-4}$ to $1x10^{-7}$
Toxic Substances Control Act	Chemicals manufactured or imported into the United States	Unreasonable risk	$1x10^{-4}$ (inferred, absent clear policy)
Occupational Safety and Health Act	Worker protection	Significant risk over 45-year working life	$1x10^{-3}$
Comprehensive Environmental Response, Compensation, and Liability Act, or Superfund	Uncontrolled hazardous waste sites	No significant risk	$1x10^{-4}$ to $1x10^{-6}$

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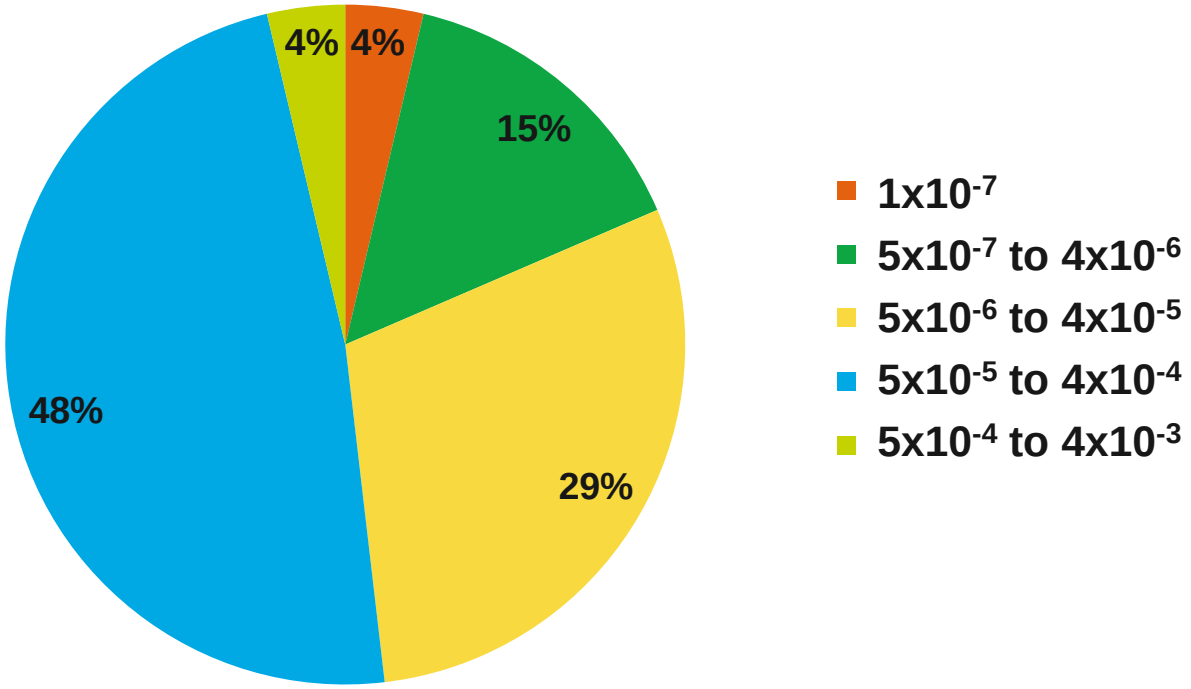
Approximate Risk Levels Associated with MCLs for Drinking Water



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Estimating Cancer Incidence in a Population

To estimate the number of cancers from chemicals in the environment one can't use the exposures (and risks) estimated in a typical EPA risk assessment.

Unless one determines the arithmetic average exposure and risk, the calculation will overestimate population exposure and risk.

Example 1: Drinking Water Intake

Range Percentiles	Midpoint Percentile	Midpoint DI (L/day)	N	Total Intake (DI x N) (L/day)	Excess Lifetime Cancer Risk	Annual Cancer Incidence
0% - 2.5%	1%	0.0189	2500	4.7E+01	2.4E-07	8.4E-06
2.5% - 7.5%	5%	0.0931	5000	4.7E+02	2.3E-06	1.7E-04
7.5% - 12.5%	10%	0.184	5000	9.2E+02	4.6E-06	3.3E-04
12.5% - 17.5%	15%	0.275	5000	1.4E+03	6.9E-06	4.9E-04
17.5% - 22.5%	20%	0.367	5000	1.8E+03	9.2E-06	6.6E-04
22.5% - 27.5%	25%	0.46	5000	2.3E+03	1.2E-05	8.2E-04
27.5% - 32.5%	30%	0.555	5000	2.8E+03	1.4E-05	9.9E-04
32.5% - 37.5%	35%	0.654	5000	3.3E+03	1.6E-05	1.2E-03
37.5% - 42.5%	40%	0.757	5000	3.8E+03	1.9E-05	1.4E-03
42.5% - 47.5%	45%	0.865	5000	4.3E+03	2.2E-05	1.5E-03
47.5% - 52.5%	50%	0.98	5000	4.9E+03	2.5E-05	1.8E-03
52.5% - 57.5%	55%	1.1	5000	5.5E+03	2.8E-05	2.0E-03
57.5% - 62.5%	60%	1.23	5000	6.2E+03	3.1E-05	2.2E-03
62.5% - 67.5%	65%	1.38	5000	6.9E+03	3.5E-05	2.5E-03
67.5% - 72.5%	70%	1.54	5000	7.7E+03	3.9E-05	2.8E-03
72.5% - 77.5%	75%	1.72	5000	8.6E+03	4.3E-05	3.1E-03
77.5% - 82.5%	80%	1.94	5000	9.7E+03	4.9E-05	3.5E-03
82.5% - 87.5%	85%	2.21	5000	1.1E+04	5.5E-05	3.9E-03
87.5% - 92.5%	90%	2.56	5000	1.3E+04	6.4E-05	4.6E-03
92.5% - 97.5%	95%	3.11	5000	1.6E+04	7.8E-05	5.6E-03
97.5% - 100%	99%	4.19	2500	1.0E+04	5.2E-05	1.9E-03
		Sum:	100000	**1.2E+05**	--	**0.041**

Mean:	1.21	100000	**1.2E+05**	**2.9E-05**	**0.041**
95th Percentile:	3.11	100000	**3.1E+05**	**7.8E-05**	**0.11**

Compare:

Annual cancer incidence of 0.041 vs. 0.11

Example 2: Fish Consumption Rate

Range Percentiles	Midpoint Percentile	Midpoint FCR (g/day)	N	Total Intake (FCR x N) (g/day)	Excess Lifetime Cancer Risk	Annual Cancer Incidence
0% - 2.5%	1%	0.283	2500	7.1E+02	3.5E-07	1.3E-05
2.5% - 7.5%	5%	1.01	5000	5.1E+03	2.5E-06	1.8E-04
7.5% - 12.5%	10%	1.72	5000	8.6E+03	4.3E-06	3.1E-04
12.5% - 17.5%	15%	2.4	5000	1.2E+04	6.0E-06	4.3E-04
17.5% - 22.5%	20%	3.09	5000	1.5E+04	7.7E-06	5.5E-04
22.5% - 27.5%	25%	3.82	5000	1.9E+04	9.6E-06	6.8E-04
27.5% - 32.5%	30%	4.61	5000	2.3E+04	1.2E-05	8.2E-04
32.5% - 37.5%	35%	5.47	5000	2.7E+04	1.4E-05	9.8E-04
37.5% - 42.5%	40%	6.44	5000	3.2E+04	1.6E-05	1.2E-03
42.5% - 47.5%	45%	7.53	5000	3.8E+04	1.9E-05	1.3E-03
47.5% - 52.5%	50%	8.78	5000	4.4E+04	2.2E-05	1.6E-03
52.5% - 57.5%	55%	10.2	5000	5.1E+04	2.6E-05	1.8E-03
57.5% - 62.5%	60%	12	5000	6.0E+04	3.0E-05	2.1E-03
62.5% - 67.5%	65%	14	5000	7.0E+04	3.5E-05	2.5E-03
67.5% - 72.5%	70%	16.6	5000	8.3E+04	4.2E-05	3.0E-03
72.5% - 77.5%	75%	19.8	5000	9.9E+04	5.0E-05	3.5E-03
77.5% - 82.5%	80%	24.2	5000	1.2E+05	6.1E-05	4.3E-03
82.5% - 87.5%	85%	30.3	5000	1.5E+05	7.6E-05	5.4E-03
87.5% - 92.5%	90%	39.9	5000	2.0E+05	1.0E-04	7.1E-03
92.5% - 97.5%	95%	58.7	5000	2.9E+05	1.5E-04	1.0E-02
97.5% - 100%	99%	112	2500	2.8E+05	1.4E-04	5.0E-03
		Sum:	100000	**1.6E+06**	--	**0.056**

Mean:	16.1	100000	**1.6E+06**	**3.9E-05**	**0.056**
95th Percentile:	58.7	100000	**5.9E+06**	**1.5E-04**	**0.21**

Compare:

Annual cancer incidence of 0.056 vs. 0.21

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Perspectives on target risk: Number of cancers

- Each incidence of cancer is tragic
- Cancer is common
- The increased incidence associated with typically used target risks is immeasurable when compared to background occurrence
- This is even true for the “less stringent” target risks

Background Cancer Incidence Compared to Hypothetical Cancer Incidence Associated With a Range of Target Risks

Region	2014 Population (millions)	2014 Background Cancer Incidence	Hypothetical Increased Cancer Incidence per Year			
			$1x10^{-7}$	$1x10^{-6}$	$1x10^{-5}$	$1x10^{-4}$
United States	318.9	1,665,540	0.5	5	46	456
Florida	19.89	114,560	0.03	0.3	3	28
Washington	7.06	38,230	0.01	0.1	1	10
Idaho	1.63	7,990	0.002	0.02	0.2	2

American Cancer Society. 2016. Cancer Facts & Figures 2014. Retrieved June 03, 2016, from http://www.cancer.org/research/cancerfactsstatistics/cancerfactsfigures2014/

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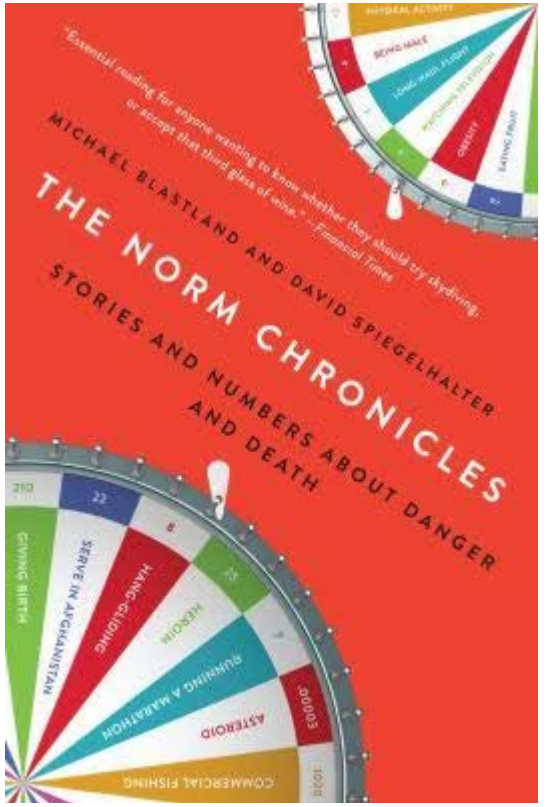
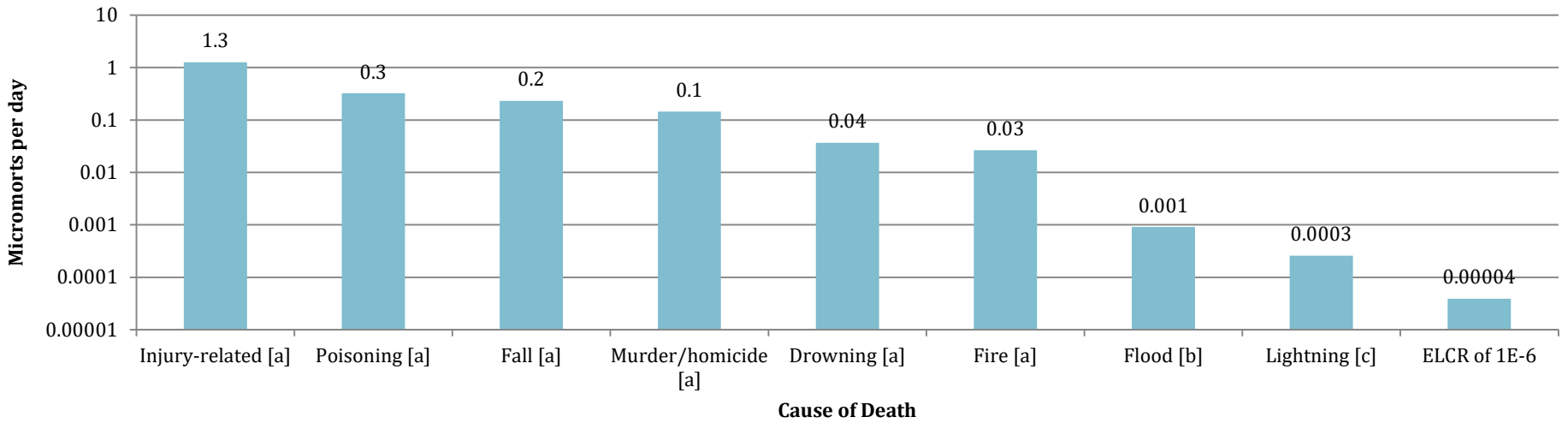
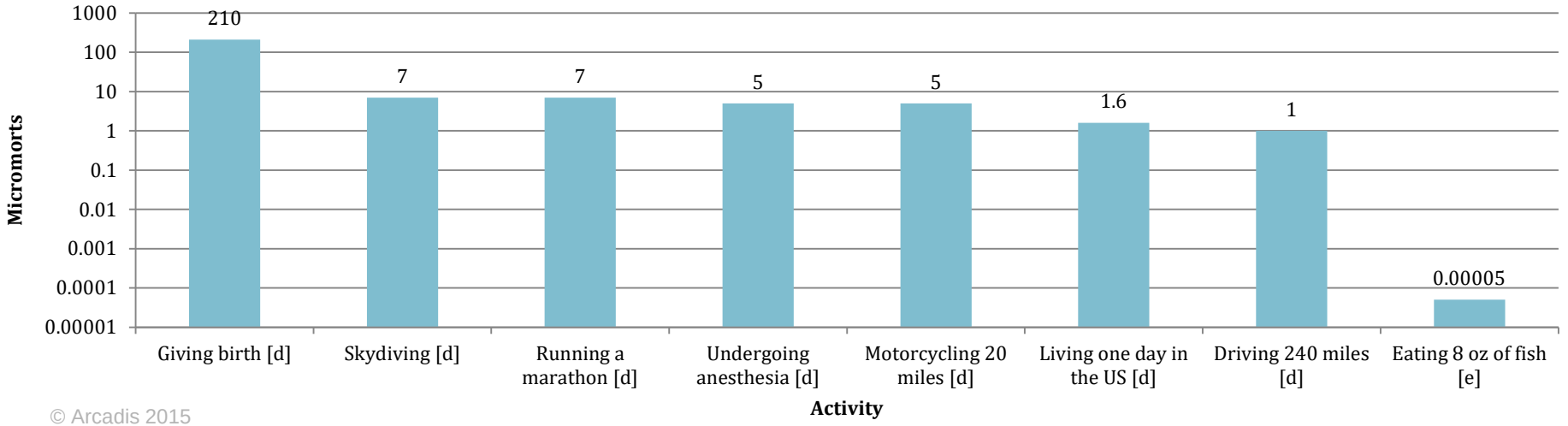
Perspectives on target risk: Micromorts

- A one in one million probability of death
- Developed by Prof. Ron Howard of Stanford
- Described wonderfully by David Speigelhalter and Michael Blastland in “The Norm Chronicles: Stories and Numbers about Danger and Death”
- Our daily lives are filled with micromorts, why are higher target risks not acceptable?



Perspectives on target risk: Micromorts





a. Murphy, S.L., J. Xu, and K.D. Kochanek. 2013. Deaths: final data for 2010. National Vital Statistics Reports 61(4):1-118.

b. National Oceanic and Atmospheric Administrator (NOAA). 2015a. Flood Fatality Data. Accessible via: http://www.nws.noaa.gov/hic/flood_stats/recent_individual_deaths.shtml (January).

c. NOAA. 2015b. Lightning Fatalities. Accessible via: http://www.lightningsafety.noaa.gov/fatalities.htm (January).

d. Blastland, M. and D. Spiegelhalter. 2014. The Norm Chronicles: Stories and Numbers about Danger and Death. Basic Books.

e. Assuming organism-only AWQC are based on a fish consumption rate of 175 grams per day and risk level of $1x10^{-6}$.

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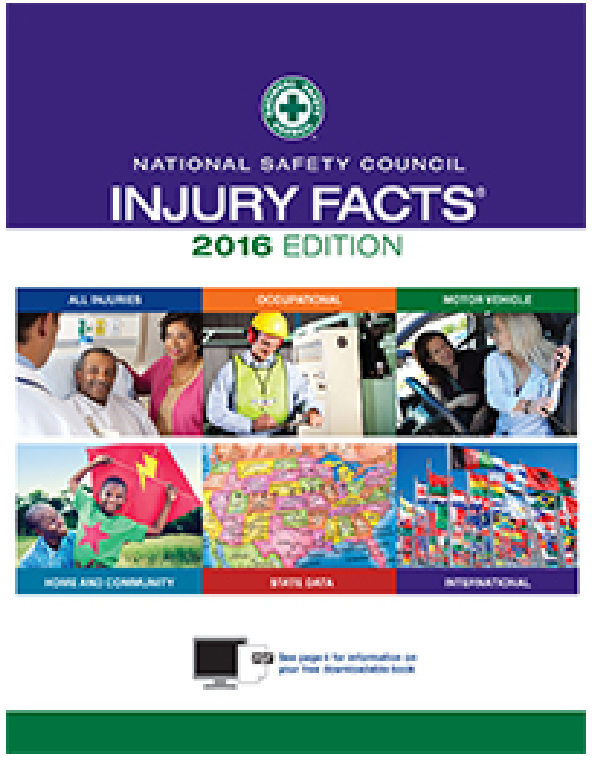
Perspectives on target risk: Deaths from Injuries

- People don’t choose to die from injuries and accidents
- National Safety Council tracks deaths from injuries
- Publishes “Injury Facts” every year http://www.nsc.org/learn/safety-knowledge/Pages/injury-facts.aspx
- Cancer incidence associated with typically used target risks similar to or lower than least likely causes tracked by NSC



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Odds of dying

Cause of Death	Odds of Dying	Lifetime Risk
Living	1 in 1	1
Heart Disease and Cancer	1 in 7	$1.4x10^{-1}$
Chronic Lower Respiratory Disease	1 in 27	$3.7x10^{-2}$
Intentional Self-harm	1 in 97	$1.0x10^{-2}$
Unintentional Poisoning By and Exposure to Noxious Substances	1 in 103	$9.7x10^{-3}$
Motor Vehicle Crash	1 in 113	$8.8x10^{-3}$
Fall	1 in 133	$7.5x10^{-3}$
Assault by Firearm	1 in 358	$2.8x10^{-3}$
Pedestrian Incident	1 in 672	$1.5x10^{-3}$
Unintentional Drowning and Submersion	1 in 1,183	$8.5x10^{-4}$
Exposure to Fire, Flames or Smoke	1 in 1,454	$6.9x10^{-4}$
Choking from Inhalation and Ingestion of Food	1 in 3,408	$2.9x10^{-4}$
Pedacyclist Incident	1 in 4,337	$2.3x10^{-4}$
Exposure to Excessive Natural Heat	1 in 10,784	$9.3x10^{-5}$
Exposure to Electric Current, Radiation, Temperature and Pressure	1 in 14,695	$6.8x10^{-5}$
Cataclysmic Storm	1 in 63,679	$1.6x10^{-5}$
Contact with Hornets, Wasps and Bees	1 in 64,706	$1.5x10^{-5}$
Being Bitten or Struck by a Dog	1 in 114,622	$8.7x10^{-6}$
Lightning Strike	1 in 174,426	$5.7x10^{-6}$

Source: National Safety Council, Odds of Dying Table, 2016

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Perspectives About Causes of Death

a. As reported by the Detailed Tables for the National Vital Statistics Report (NVSR) "Deaths: Final Data for 2013." Accessible via http://www.cdc.gov/nchs/data/nvsr/nvsr64/nvsr64_02.pdf.
b. Range of expected fatalities is 10-100x times lower than allowable risk level to account for overestimate of risk to the average member of the population.
c.4% of the population lives within a mile of a CERCLA site. "Population Surrounding 1388 Superfund Remedial Sites. OSWER/Office of Communications, Partnerships, and Analysis September 2015."

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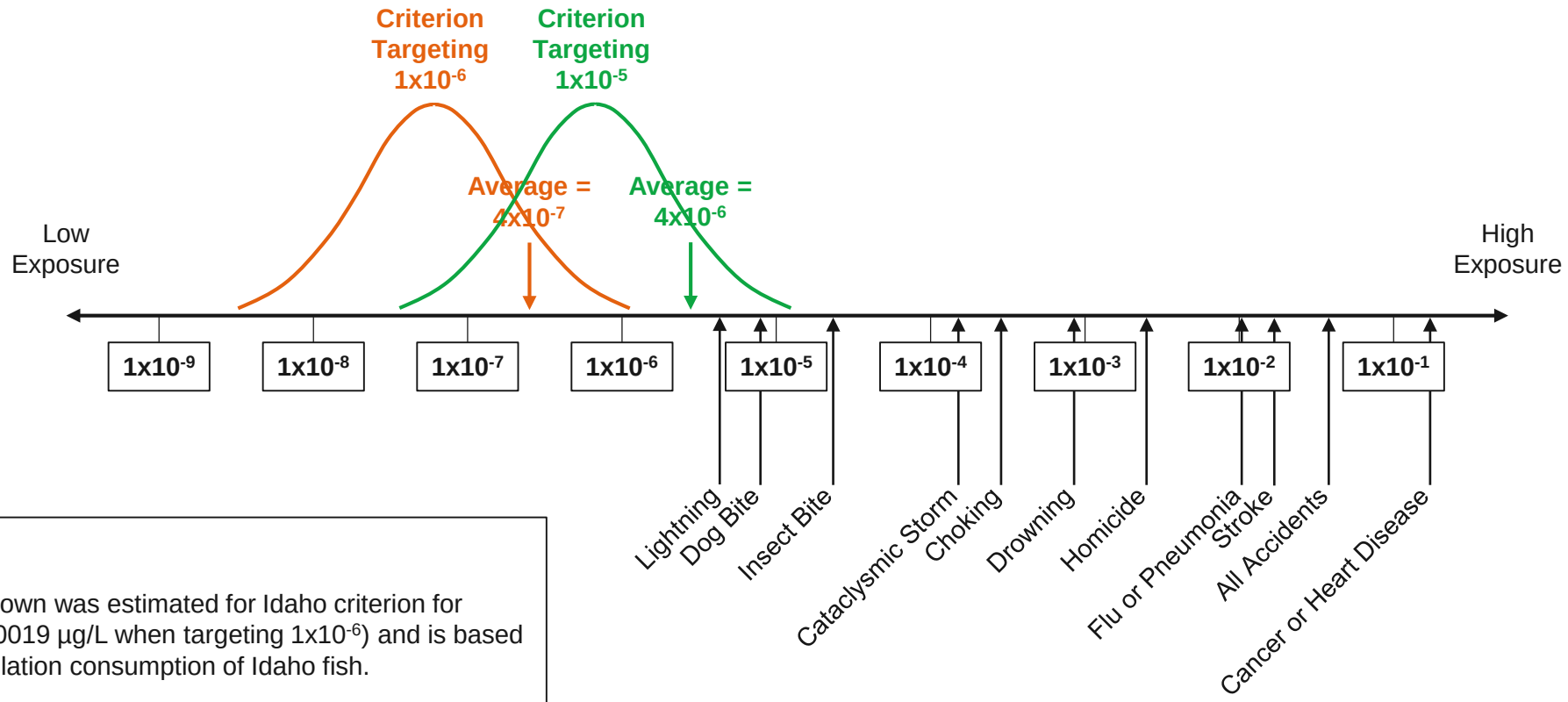
Protectiveness of HHWQC



Notes:

Risk distribution shown was estimated for Idaho criterion for PCBs (WQC = 0.00019 µg/L when targeting $1x10^{-6}$) and is based on state-wide population consumption of Idaho fish.

Risk distributions associated with WQC represent cancer incidence, not mortality. Therefore, the risk distributions overstate the risk of death from cancer associated with WQC.

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Improving Public Health Decision-Making

- Realization and acknowledgment of the existence of a range of risk from chemicals in the environment – *we are not the same*.
- Understanding the magnitude of various causes of death.
- Appreciating the balance between limited resources and the benefits derived from decisions that affect public health.
- Open and transparent dialogue about who we are protecting, at what allowable risk level(s), and why.
- The dialogue and decisions are difficult.

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Societal norms: Acceptance of causes of cancer

- In 2009 562,340 people in the US died of cancer.[a]
- Approximately 3.5% of these deaths, about 19,500 people, were attributed to a specific cause.[b]
- The US population in 2009 was about 310,000,000 people. That leads to a per capita cancer risk of about 6.3×10^{-5} from this cause.
- Per capita consumption of this cause was about 8.7 kg/year in 2009 (about 24 grams a day, or about 0.8 ounces per day).
- What is this cause?
- Insight into what we (society) consider acceptable.

[a] Cancer Facts and Figures 2009, American Cancer Society

[b] National Cancer Institute, Fact Sheet about this cause of cancer (reviewed June 24, 2013)

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QUESTIONS / DISCUSSION