Tighter Controls on Environmental/Occupational Carcinogens in the Wake of the PCP Report?

Not Without More Work

The Collaborative on Health and the Environment: Conference Call

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Four Themes for my Remarks (if time permits):

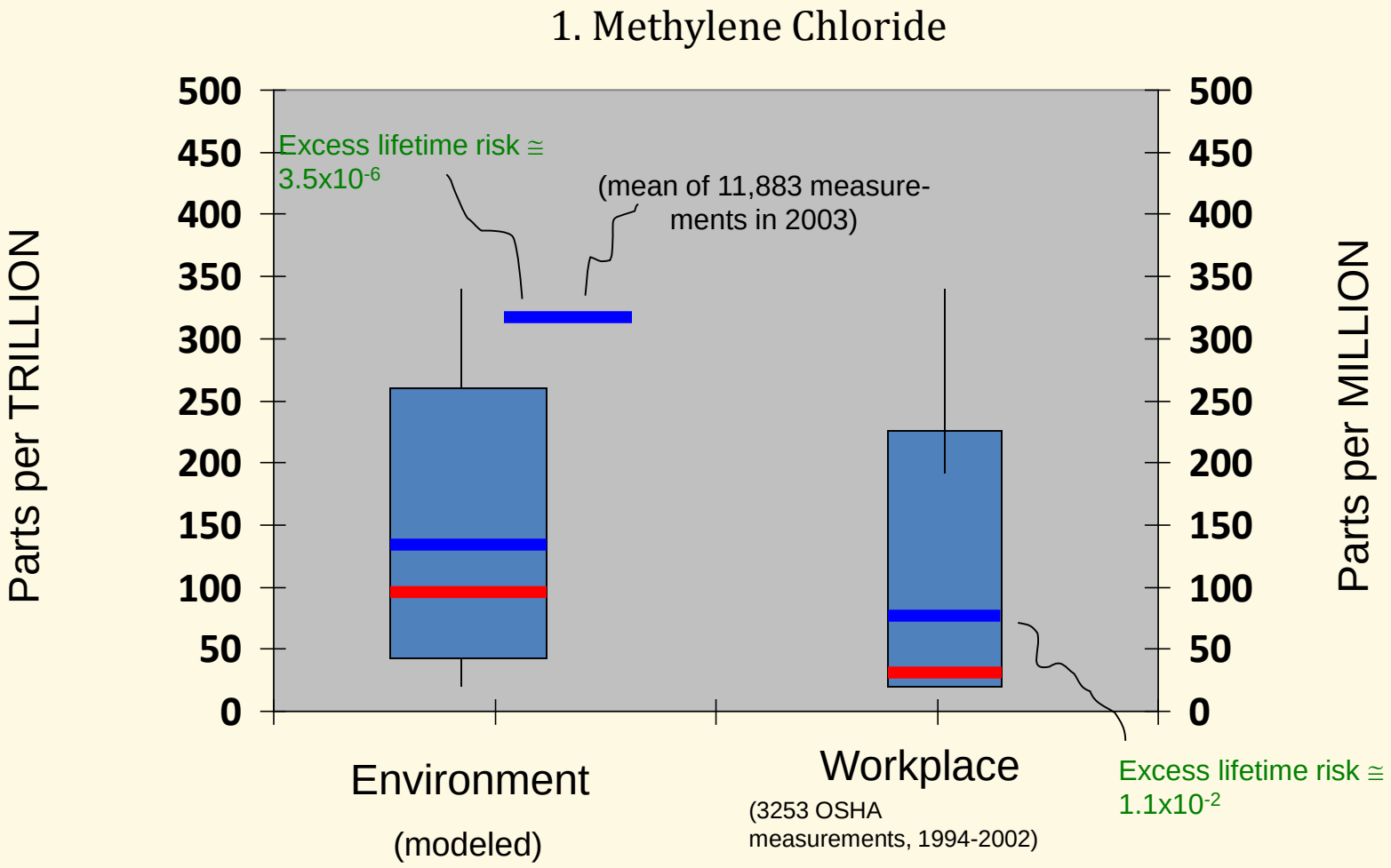
1. It's not an either/or, but exposures and cancer risks in the workplace *dwarf* those in the general environment– and yet OSHA and the rest of U.S. society continue to fail to make progress here;

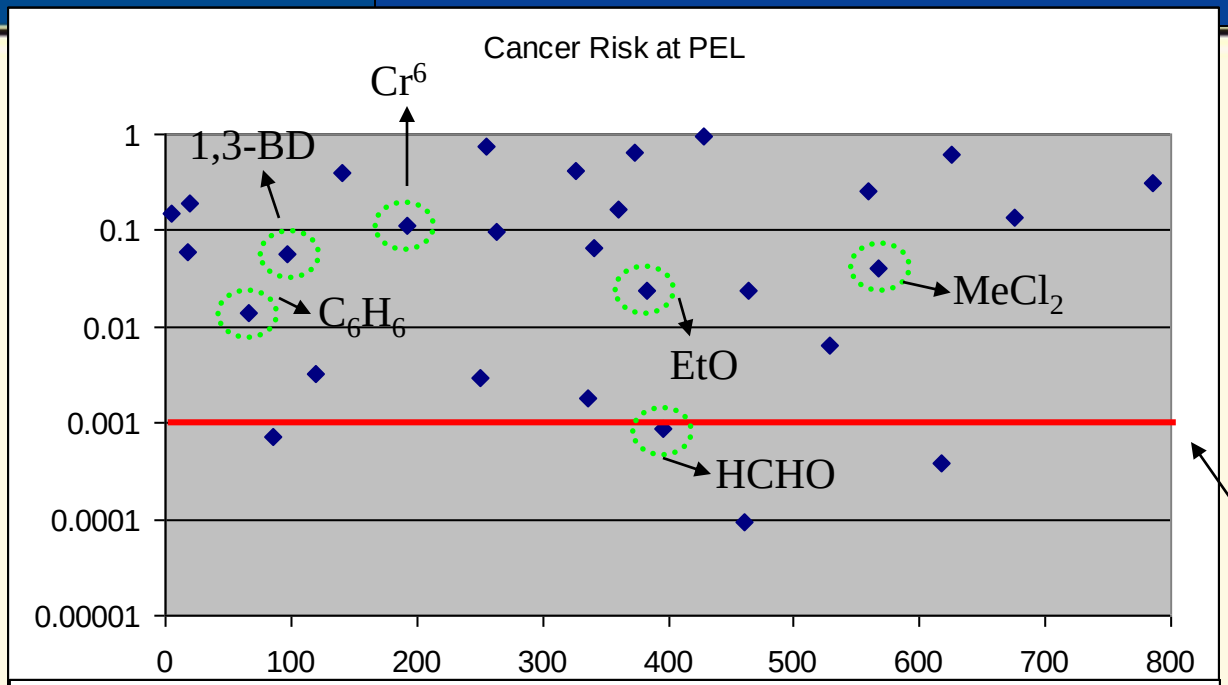
2. Meanwhile, EPA is approaching thirty years of ignoring one of the most basic features of carcinogen risk assessment– that its current procedures *underestimate* risk for millions of humans whose susceptibility to cancer exceeds the population average;

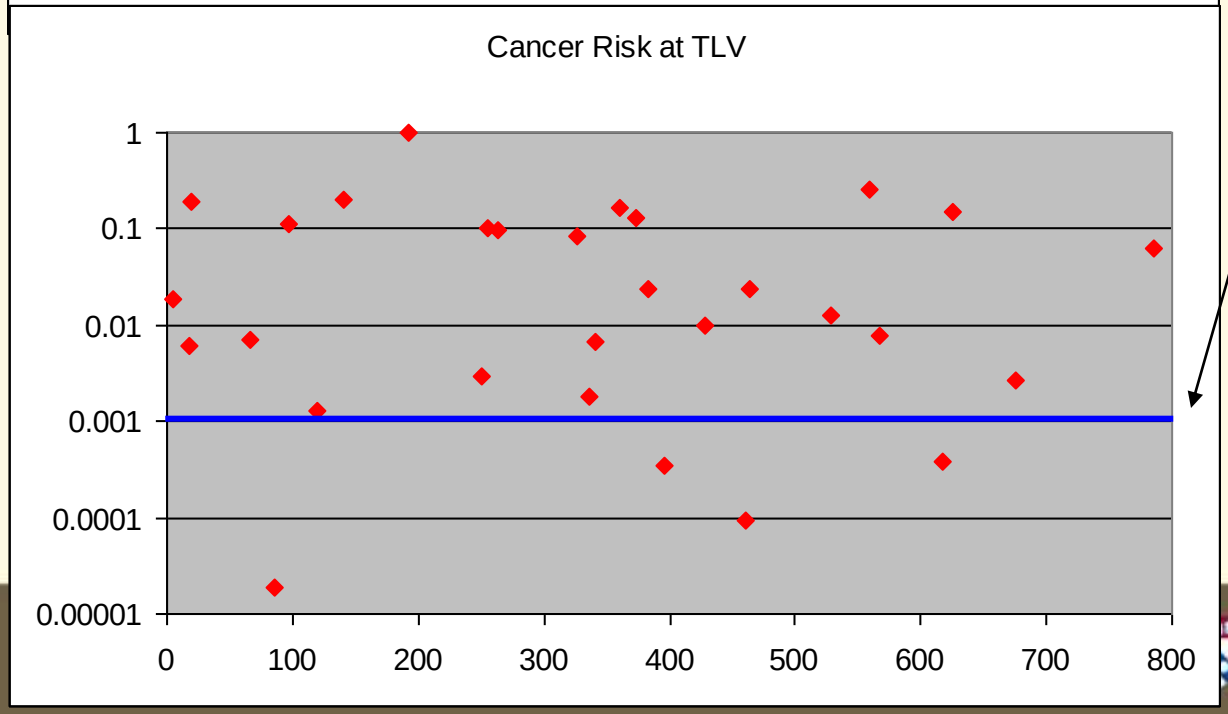
3. Comparing the costs and benefits of regulatory and other controls is the only reasonable way (logically and strategically) to make social decisions (neither blind precaution nor deaf denial will do); and

4. We need to consider methods that envision and analyze bold solutions to environmental health problems (as opposed to mere arguments about their magnitude and substance-by-substance controls)

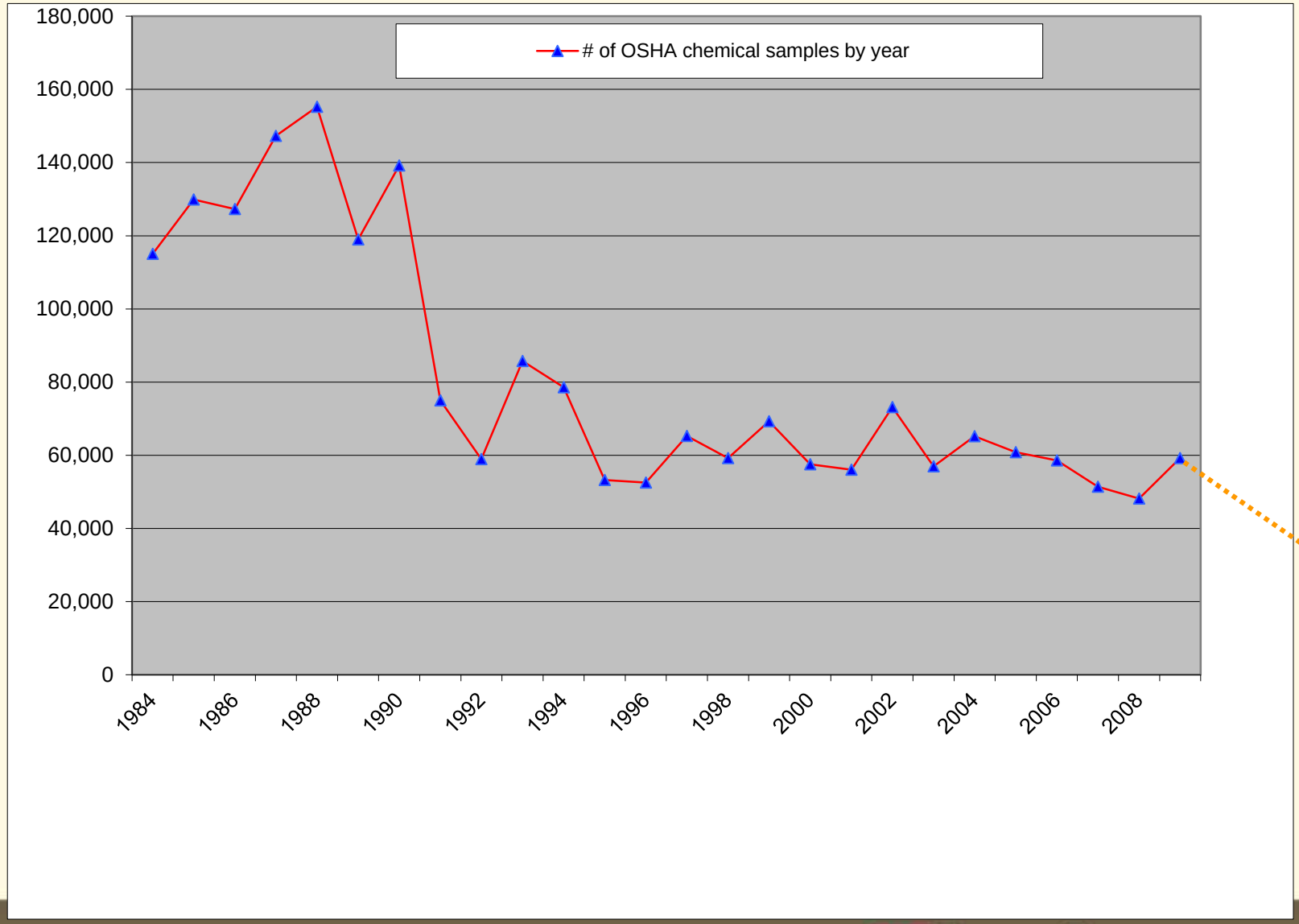
Kilo-Disparities, Mega-Disparities: 3 Cases







1/1000: uppermost end of Supreme Court acceptable risk range in *Benzene*


180,000
160,000
140,000
120,000
100,000
80,000
60,000
40,000
20,000
0
# of OSHA chemical samples by year
1984
1986
1988
1990
1992
1994
1996
1998
2000
2002
2004
2006
2008

OSHA Enforcement Activity, Selected Health and Safety Standards

(Oct. 2006- Sept. 2007, federal programs only (24 states)

Standard	# of Inspections with violations	# of citations	Total $ amount of penalties
All 1910.1000 combined ("Z-table" of PELs)	173	348	$365,000
Asbestos	77	147	$205,220
Chromium (VI)	74	225	$113,000
Methylene chloride	71	258	$131,000
Formaldehyde	52	136	$74,000
Cadmium	24	73	$27,000
Benzene	3	11	$8,000
Ethylene oxide	2	20	$97,000
General reqts. for scaffolds	4,050	11,000	$10,000,000

And OSHA *RARELY* ISSUES "GENERAL DUTY CLAUSE" VIOLATIONS FOR HEALTH HAZARDS

From 1998-2008 (federal and state-run programs combined), OSHA issued **19,894** GDC violations. Of these, …

- One (1) cited overexposure to a carcinogen (ß-estradiol at a drug co.)
- Six (6) cited risk of cancer (2 for sunlight, 1 for wood dust, 1 for TCDD, 2 for cytotoxic drugs)
- Thirty (30) cited any exceedance of any TLV®
  - 8 of these were for heat stress
  - 6 were for ammonia
  - 1 each for CO, welding fume, $FeSO_4$, R-123, MDI

[37/19894 < 0.2%]

From Politi, Arena, Schwerha, and Sussman, *Journal of Occupational and Environmental Medicine*, **46:** 550-555, 2004:

Category	Percent of Hospital Admission Records Containing Info.
Gender	99.9
Age	99.1
Smoking History	76.0
Cancer History	42.9
Occupational History	27.8

1-Bromopropane: Ample Data, no PEL, no IRIS Entry

1999– reproductive LOAEL (animals): 200 ppm

1999– nominated for NTP bioassay by OSHA

1999– Swiss circuit board maker ceases use of 1-BP: "there is a weight of evidence that should sound warning bells to any thinking person."

2002-04– case reports of irreversible neuropathy in workers at ≅ 100 ppm

2004– human LOAEL (loss of vibratory sense in toes): 1.1 ppm

2009– NTP bioassay published; 9/50 female mouse lung tumors (1/50 controls) at 62.5 ppm [$q_1^* \cong 2 \times 10^{-3}$ per ppm]

2010– "60 female workers in four 1-BP factories demonstrated dose-dependent neurological and hematological effects of 1-BP exposure with a LOAEL of 1.28 ppm for loss of vibration sense in toes"

(from EPA Cancer Risk Assessment Guidelines, 2005)

The linear default is thought to generally provide an upper-bound calculation of potential risk at low doses, for example, a 1/100,000 to 1/1,000,000 risk. This upper bound is thought to be public-health protective at low doses for the range of human variation, considering the typical Agency target range for risk management of 1/1,000,000 to 1/10,000, although it may not completely be so (Bois et al., 1995) if pre-existing disease or genetic constitution place a percentage of the population at greater risk from exposure to carcinogens. The question of what may be the actual variation in human susceptibility is one that was discussed in general in the NRC (1994) report, as well as the NRC report on pesticides in children and infants (NRC, 1993b). NRC has recommended research on the question, and EPA and other agencies are conducting such research. Given the current state of knowledge, EPA will assume that the linear default procedure adequately accounts for human variation unless there is case-specific information for a given agent or mode of action that indicates a particularly susceptible subpopulation or lifestage, in which case the special information will be used.

NAS "Science and Decisions, 2009

An assumption that the distribution is lognormal is reasonable, as is an assumption of a difference of a factor of 10 to 50 between the median and upper 95th percentile people… *It is clear that the difference is significantly greater than the factor of 1, the current implicit assumption in cancer risk assessment.* In the absence of chemical-specific information, the committee recommends that EPA adopt a default distribution or fixed adjustment value for use in cancer risk assessment. A factor of 25 would be a reasonable default value to assume as a ratio between the median and upper 95th percentile persons' cancer sensitivity.

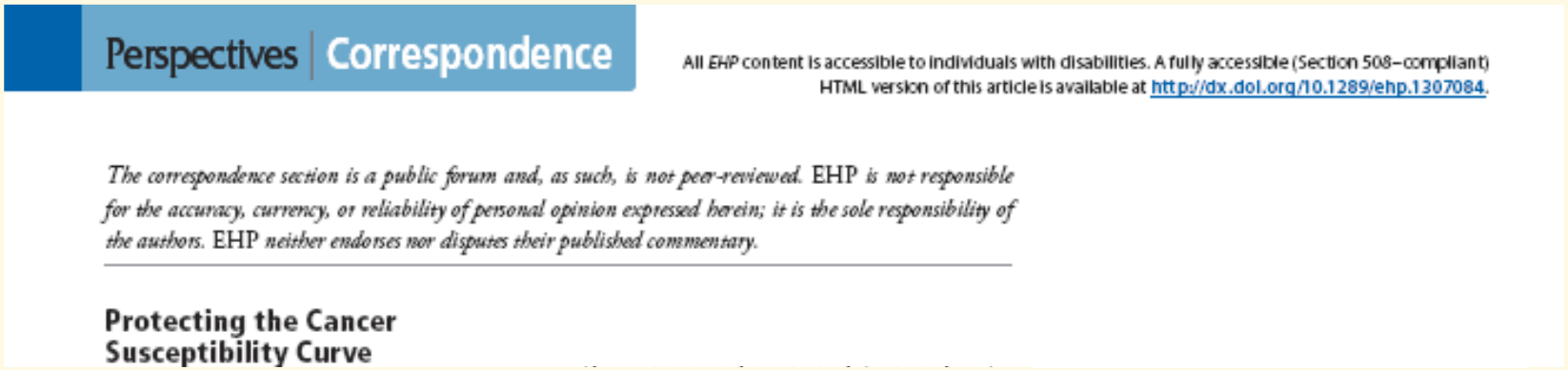
The suggested default of 25 will have the effect of increasing the population risk (average risk) relative to the median person's risk by a factor of 6.8. If the risk to the median human were estimated to be 10^{-6}, and a population of one million persons were exposed, the expected number of cases of cancer would be 6.8 rather than 1.0.

EPA Underestimates, Oversimplifies, Miscommunicates, and Mismanages Cancer Risks by Ignoring Human Susceptibility

Adam M. Finkel*

"I continue to worry about the underestimation of risks and the systematic overestimation of regulatory costs, each of which leads us to less ambitious controls on toxic substances than we would choose if given unbiased information. I expect other advocates to continue to stress the possibility that, instead, benefits are exaggerated and costs are understated– to the extent they can do so without doing violence to the facts.

But I remain puzzled why an agency tasked by Congress with meeting individual-risk goals would declare "Mission Accomplished" without sufficient reason, and I am even more puzzled why an agency beleaguered by claims that its regulations do not have benefits in excess of costs would systematically preside over the understating of those very benefits."



Perspectives | Correspondence

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Protecting the Cancer Susceptibility Curve

"Why might the U.S. EPA and its stakeholders be spending so much effort refining allometric scaling procedures, dialing back the estimation of exposure to the maximally exposed individual, and positing sophisticated nonlinear modes of action, while continuing to make the unscientific assertion that we are all equally susceptible to carcinogenesis? I observe that the first three improvements tend to result in lower estimated risk and less environmental protection, whereas shining a light on human variation in cancer susceptibility would tend to have the opposite effect on risk estimates.

We should be advancing sound science along all fronts, not only the areas that support one type of policy preference."

Traditional risk assessment asks a narrow kind of question: “What allowable concentrations of each of 5 different chemicals should we allow in our plastic water bottles?” “Solution-Focused Risk Assessment,” in contrast, poses a more ambitious question: “How might we provide ready access to cold drinking water, perhaps with 29 billion FEWER bottles *of any kind* bought and thrown away each year?”