"New TSCA" after Three Years: Too Much Like "Classic TSCA"

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Covering Much TSCA Ground, Quickly:

1. EPA has often ***under***estimated health risks of chemicals (despite unscientific claims of the opposite)– but now the dominant mode is *delay* and "buffing" rather than completing risk assessments.

2. TSCA requires EPA to reduce unreasonable risks to workers, but the Agency is contorting the law and the science to avoid this—Methylene Chloride ($MeCl_2$) as a case example.

3. Congress failed to define "unreasonable risk" under the Lautenberg Act, and EPA is in no hurry to do so.

Many factors inherent to the methods used by EPA and other agencies tend to underestimate cancer risk (for example, the bioassay design that in effect only exposes the test animals from ages “2” to “70” in human terms)– but the most vexing mistake EPA has made since the 1970s is this:

While *non-cancer* risk assessment has always built in two factors of 10 to adjust upwards for (1) substances for which humans are more sensitive on average than test animals are and (2) the substantial portion of the human population which are more sensitive than the typical human, ***EPA has always treated cancer risks as if all 300 million of us are identical to each other and identical (other than our size) to test animals.***

(from current (2005) EPA Cancer Risk Assessment Guidelines

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 between 10 and 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.* …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 "Trust Us, We're (Better) Scientists" Playbook of Manufactured Doubt:

Claim	Refutation
The substance "has a threshold," so it's somehow less/not important	Unless it is a "magic threshold"– one that appears within the narrow window between current exposures and desired exposures, this claim changes NOTHING about risk!
The substance is (or is alleged to be) non-genotoxic	Non-mutagens can be carcinogenic or otherwise toxic.
"Pay no attention to the dead mice/rats because humans are different"	Sometimes a very valid argument, WHEN data and theory support it plausibly.
No statistically significant epidemiology, so not "really" a carcinogen/toxicant	Epidemiology is great for rare diseases with potent environmental causes; otherwise, it can be "looking at Jupiter with binoculars."
If there is epidemiology, don't believe it "because confounding"	True confounding is much less common than skeptics claim.
Don't bother testing it because we know from structure-activity theory it is benign.	Embarrassing history of past mistakes.

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Derivation of an Occupational Exposure Limit (OEL) for n-Propyl Bromide Using an Improved Methodology

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The lack of genetic toxicity of n-propyl bromide in all but one test performed is also in agreement with the structure activity analysis for acute and subchronic toxicities showing that $CH_3Br > CH_3CH_2Br > CH_3CH_2CH_2Br$ for genotoxicity. Therefore, it can be expected with confidence that if a carcinogenicity bioassay were to be conducted with n-propyl bromide at levels used in the ethyl bromide bioassay the outcome would be negative. Thus, even in the absence of a chronic bioassay it is clear that carcinogenicity is not an issue with n-propyl bromide because it could be only a very high dose effect or it would be not demonstrable. In agreement with this view is the finding that

There is no substitute for actually gathering the data: otherwise, embarrassing "predictions" may ensue…

The human NOEL for n-propyl bromide–induced headache is reported to be 170 ppm.[31] Since the size of the population in that study was small, the use of a safety factor of two should be applied to protect nearly all workers, and a safety factor of three would be appropriate to provide a larger margin of safety from this adverse effect. Therefore, the recommended OEL for n-propyl bromide should be in the range of 60 to 90 ppm.

TABLE 2
Estimated Number of Disease Deaths, Nonfatal Cases, and
2007

Disease and Subcategories	Number of Deaths and Cases Percentage (of column) for Deaths Only
Fatal diseases	
Respiratory diseases	
Pneumoconiosis	985 (1.8%)
Asthma	591 (1.1%)
Chronic obstructive pulmonary disease (COPD)	18,411 (34.4%)
Pulmonary tuberculosis	25 (<0.1%)
Cancer	
Lung cancer	15,366 (28.8%)
Bladder cancer	1642 (3.1%)
Mesothelioma	2194 (4.1%)
Leukemia	369 (0.7%)
Laryngeal cancer	313 (0.6%)
Skin cancer	66 (0.1%)
Sinonasal cancer	116 (0.2%)
Nasopharynx cancer	148 (0.3%)
Kidney cancer	93 (0.2%)
Liver cancer	79 (0.1%)
All cancers combined	20,386 (38.1%)
Circulatory disease	
Coronary heart disease due to job control, shift work, or noise[a]	9,809 (18.4%)
Coronary heart disease due to environmental tobacco smoke[a]	2,415 (4.5%)
Stroke due to noise[a]	80 (0.1%)
All circulatory diseases	12,304 (23.0%)
All other diseases	
Renal disease	636 (1.2%)
Liver disease from hepatitis B and C	107 (0.2%)
Subtotal for fatal diseases	53,445

J. Paul Leigh, 2011, "Economic Burden of Occupational Injury and Illness in the United States, *Millbank Quarterly,* 89(4); 728-772.

(citing Steenland, K., C. Burnett, N. Lalich, E. Ward, and J. Hurrell. 2003. "Dying for Work: The Magnitude of US Mortality from Selected Causes of Deaths Associated with Occupation." *American Journal of Industrial Medicine* 43(5):461–82.)

Number of deaths for leading causes of death

- Heart disease: 614,348
- Cancer: 591,699
- Chronic lower respiratory diseases: 147,101
- Accidents (unintentional injuries): 136,053
- Stroke (cerebrovascular diseases): 133,103
- Alzheimer's disease: 93,541
- Diabetes: 76,488
- Influenza and pneumonia: 55,227
- Nephritis, nephrotic syndrome, and nephrosis: 48,146
- Intentional self-harm (suicide): 42,773

Source: Health United States, 2015 Table 19 [PDF- 9.8 MB] (Data are for 2014)

Supreme Court Guidance from the 1980 *Benzene* Case:

- "If... the odds are one in a billion that a person will die... the risk clearly could not be considered significant."
- "On the other hand, if the odds are one in a thousand, a reasonable person might well consider the risk significant."
- (10^{-3} / 10^{-9} = 1,000,000-fold "window")

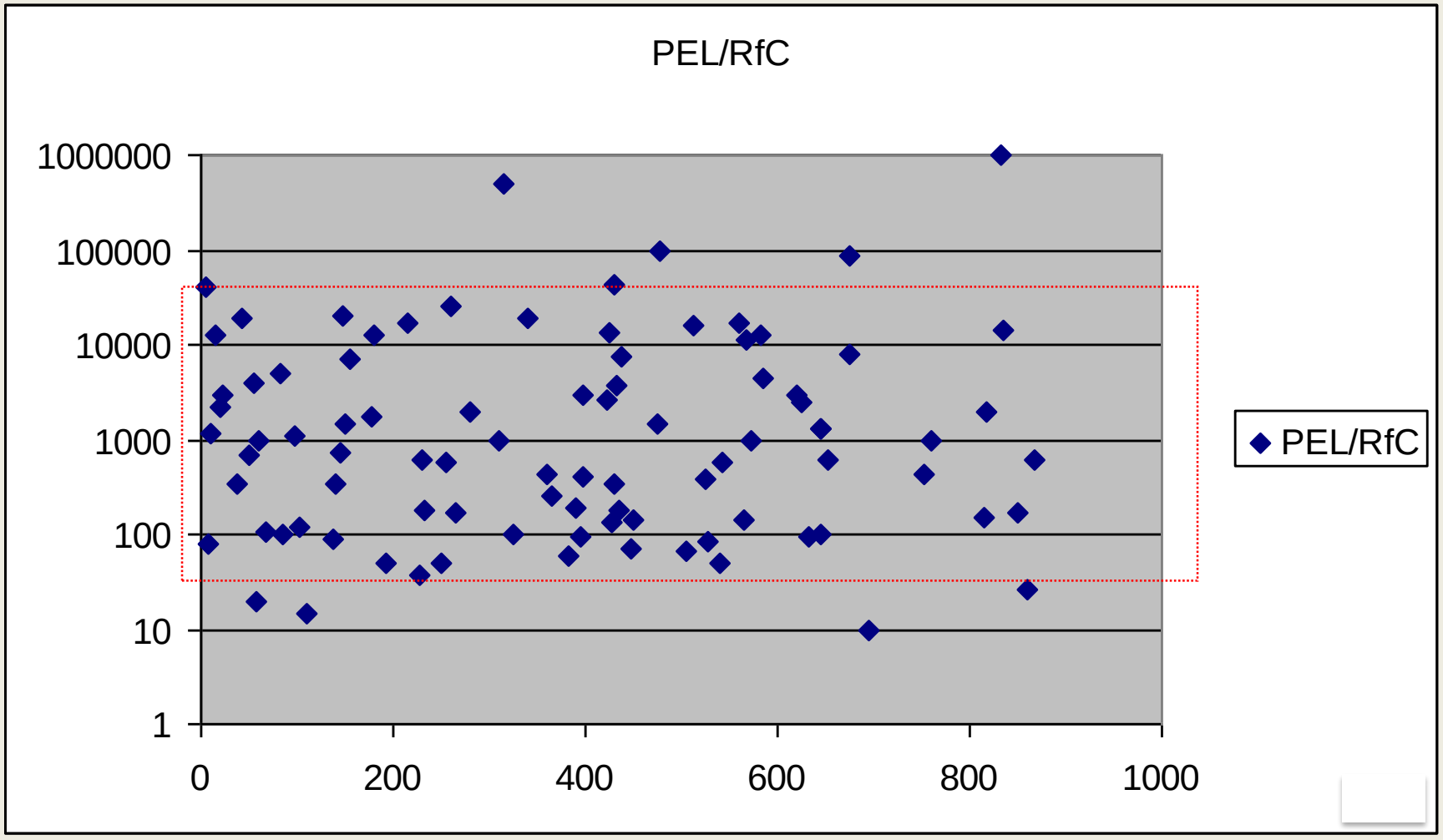
TABLE 9.6. LIFETIME EXCESS CANCER RISKS ASSOCIATED WITH ALL THE OSHA SUBSTANCE-SPECIFIC PELs (SET SUBSEQUENT TO THE 1980 *BENZENE* DECISION).

Substance (Year)	Species Used for Extrapolation	Number of Workers Exposed	Risk at Old PEL	Risk at Average Exposure Level (at Time of Promulgation)	Risk at New PEL
Ethylene Oxide (1984)	Rat	71,000(directly exposed) 69,000(indirectly exposed)	(50 ppm) $63 - 109 \times 10^{-3}$	??	(1 ppm) $1.2 - 2.3 \times 10^{-3}$
Benzene (1987)	Rat/Mouse/ Human	238,000	(10 ppm) 95×10^{-3}	??	(1 ppm) 10×10^{-3}
4,4′-Methylene-dianiline (1992)	Mouse	4,000	(no prior PEL)	(70 ppb) 6×10^{-3}	(10 ppb) $8 \times 10^{-4*}$ $9 \times 10^{-4**}$
Asbestos (1992)	Human	1,316,000	(2 fibers/cm^3) 64×10^{-3}	??	(0.2 fibers/cm^3) 6.7×10^{-3}
Formaldehyde (1992)	Rat	2,160,000 (at > 0.1 ppm)	(3 ppm) $8.3 \times 10^{-3**}$ $0.07 \times 10^{-3*}$	??	(0.75 ppm) $0.006 \times 10^{-3*}$ $2.6 \times 10^{-3**}$
Cadmium (1992)	Rat/Human	525,000	(100 μg/m^3) 58×10^{-3} 157×10^{-3}	??	(5 μg/m^3) $3 \times 10^{-3} - 15 \times 10^{-3}$
1,3-Butadiene (1996)	Mouse	9,700	(1000 ppm) ?? (note: 60 ppm ≈ 99th percentile of exposure)	(1.25 ppm)	(1 ppm) 1.3×10^{-3} to 8.1×10^{-3} (multiple assessments)
Methylene Chloride (1997)	Mouse	240,000	(500 ppm) 126×10^{-3}	(43 ppm) $6.2 \times 10^{-3**}$ $2.1 \times 10^{-3*}$	(25 ppm) $3.6 \times 10^{-3**}$ $1.2 \times 10^{-3*}$
Chromium (VI) (2006)	Human	558,000	(52 μg/m^3) $100 - 350 \times 10^{-3}$	(2.75 μg/m^3) $\approx 5.5 - 25 \times 10^{-3}$	(5 μg/m^3) $10 - 45 \times 10^{-3}$

* = maximum likelihood estimate
** = 95th percentile upper confidence limit

Source: A. Finkel and P.B. Ryan (2007), Ch. 9 in **Risk Assessment for Environmental Health,** Robson and Toscano eds.)

Most of the OSHA PELs are between 50 and 50,000 times the EPA RfC

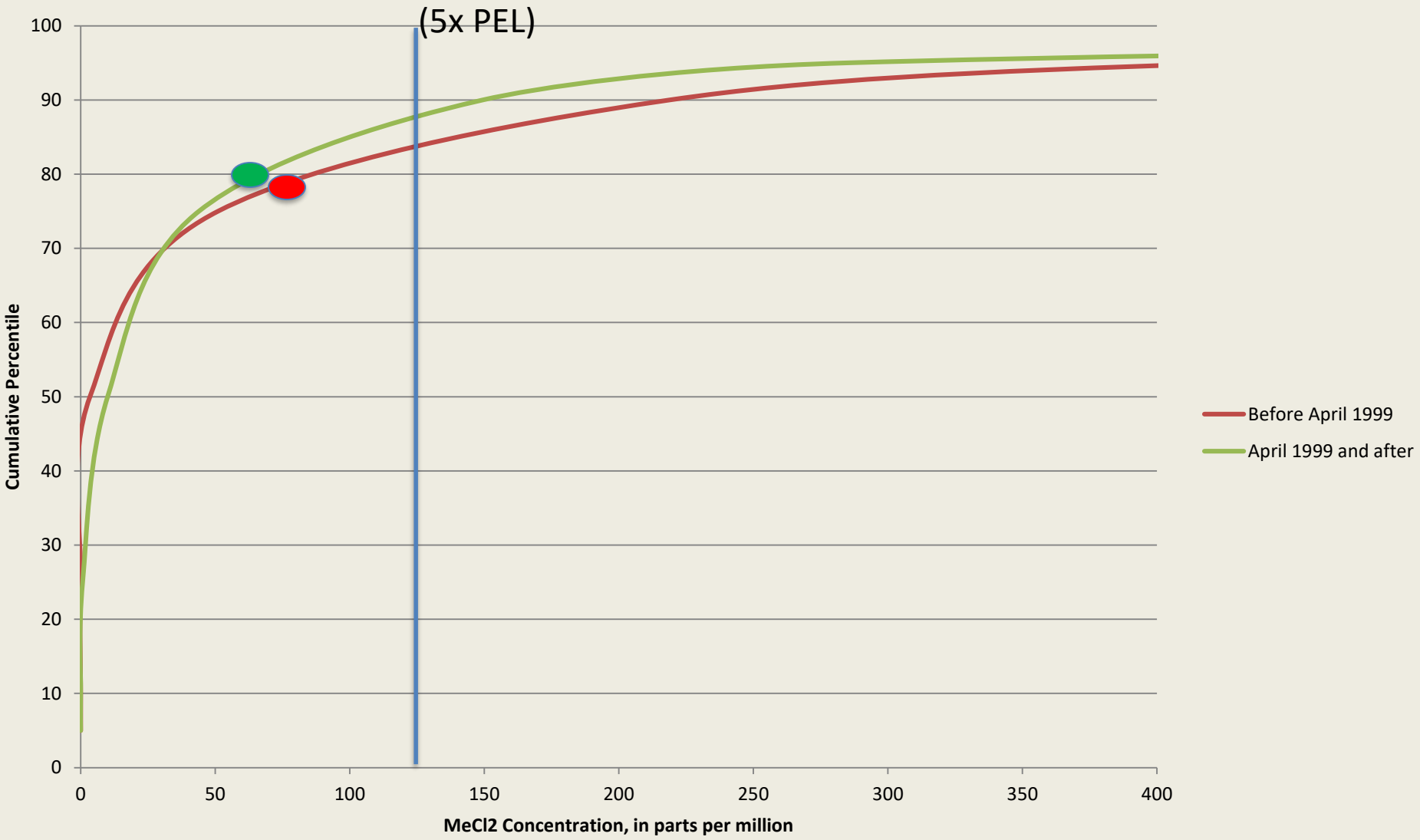


The Halogenated Solvents Industry Alliance (HSIA) claims that "there is no basis for EPA to assume that $MeCl_2$ is being used throughout the U.S. in what would be flagrant violation of the OSHA standard. This is clearly untrue: indeed, *such violations are rampant and happening before OSHA's eyes.*

HSIA offers sarcastically that "it is remarkable that EPA would even consider using pre-1997 exposure data," but the full dataset shows that the pre-1997 and post-1997 exposure distributions are more similar than different.

HSIA also cites TSCA § 9(a): "If unreasonable risk can be sufficiently reduced under a law not administered by EPA, EPA shall publish and submit to the other agency a report and request it to determine if it can reduce the risk under such other law."

But: (1) OSHA does not cover public-sector workers, independent contractors, bystanders, and DIYers; (2) the 1997 OSHA standard (whose development I led) fails utterly to "reduce unreasonable risk" below even 1/1000! (we failed to even look at a 10 ppm standard, which might have been quite feasible).



12,400 OSHA samples from 1984-2018 (EPA only used 100 of these). Average exposure dropped only slightly (from 85 ppm to 69 ppm) after 4/1999 when OSHA standard took full effect. Twelve percent of all samples exceed 125 ppm.

I have rarely seen a more brazen, more inaccurate, and more offensive statement in my 35 years in and around government as this one from ACC's March 2017 comments to EPA on the first ten TSCA chemicals:

> "given that OSHA protocols are designed to regulate risk to worker populations, it should be the unusual case where an unreasonable risk may present to a worker population under conditions of use."

I am here to emphasize that in every single case where OSHA has regulated and in every single case where OSHA has not regulated, unreasonable risks to workers do remain. Fifty thousand annual premature deaths, and workplace concentrations tens of thousands of times higher than EPA limits, attest to the willful blindness of ACC's statement and to the need for Congress to make good on its legislative amendments.

Why did Congress instruct EPA to consult with OSHA, but at its discretion? The answer is that for most or all of the chemical risks EPA finds are unreasonably high to workers, ***OSHA's accurate answer to the question "can you do more?" would be "no,"*** and so asking the question will complicate and delay a simple question of whether unreasonable risks will indeed be reduced. I have very high regard for the dedication and accomplishments of my former colleagues and staff at OSHA, but for many reasons, OSHA is simply overmatched and unable to reduce unreasonable risks.

In particular, OSHA does ***not*** require employers to follow manufacturers' recommendations contained on the Safety Data Sheet.

Specific Concerns with TSCA Actions (Inactions) over Past 12 Months:

- Methylene Chloride: “protecting” consumers by telling retailers not to sell MC to anyone who isn’t getting paid for using it; “protecting” workers by proposing, someday, a 20-minute certification program covering “safe use”
- Trichloroethylene: completed risk assessment relegated to “long-term action”
- Pigment Violet 29: concludes worker risk is “reasonable” because exposures may not exceed the OSHA “nuisance dust” standard
- New Chemicals: 86% of Significant New Use Rules in last 12 months approved without restrictions of any kind

Methylene Chloride:

On p. 7481 of the Proposal, EPA stated that "However, EPA recognizes that consumers can easily obtain products labeled for commercial use. Indeed, for many consumers, identifying a product as being for commercial use may imply greater efficacy."

"EPA viewed the costs and challenges involved in regulating distributors and ensuring that only trained and certified commercial users are able to access these paint and coating removal products as a significant limitation for this approach" (82 Federal Register No. 12, 1/19/17, p. 7474).

Problems Created by the Failure of Congress and EPA to Define "Unreasonable Risk" in TSCA, and by EPA's Refusal to even Estimate Risks for Non-Cancer Effects:

"Historically, dose-response assessments at EPA have been conducted differently for cancer and non-cancer effects, and the methods have been criticized for not providing the most useful results. Consequently, non-cancer effects have been underemphasized, especially in benefit-cost analyses. A consistent approach to risk assessment for cancer and non-cancer effects is ***scientifically feasible and needs to be implemented.***

-from NAS *Science and Decisions* report

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"Unreasonable Risk" is mentioned 20 times in the Lautenberg Act but not ONCE defined.

The most important aspect of a proper unreasonable-risk definition is that it should come to us in units of risk! EPA has failed for more than 40 years to express risks for non-cancer health effects in units of risk, instead falling back on outmoded concepts such as the "margin of exposure" or the "reference dose." These are *not* conclusions about risk, but rather are assertions (somewhat or wholly arbitrary ones) of safety. For an analogy, the "margin of exposure" is like a sign stretched across the Niagara River that tells kayakers there is a "waterfall up ahead," with no information about how close it is or how dangerous the drop; only a risk determination can shed light on those useful questions.

And even for cancer, the AMOUNT of risk that is/not acceptable is never mentioned. Neither the "Scoping" nor the "Problem Formulation" documents for 1-BP have a SINGLE risk estimate or risk-based goal in them!

Straw man proposal: <u>For health effects that are serious or grave, a risk cannot be "reasonable" unless with at least 90% confidence, at least 95% of the exposed population shall face a lifetime excess risk of 1/50,000 or less.</u>

*This definition assumes "unreasonable risk" is a ceiling value: in other words, EPA shall ensure in the risk-management phase of TSCA that these risks are **never** to be exceeded—but when risk-reduction costs are low, it shall be EPA policy to lower unreasonable risks **further**.*