We Need Risk-Based OELs– To Resuscitate the OSHA PELs (Or Not)

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Problem Statement:

- 31 years ago, the U.S. Supreme Court told OSHA to examine and control occupational health hazards using quantitative risk assessment (QRA)– right or wrong, anything less is (and has been!) vulnerable to judicial invalidation;
- In 2009, the National Academy of Sciences explained—*using methods others had developed over the previous 10 years*– how to estimate risk quantitatively for ALL serious toxic effects, not just carcinogenic ones;
- We are AWASH in occupational exposure limits– PELs, RELs, TLVs, MAKs, AEGLs, DNELs, DMELs– ***but none of them are risk-based;***
- OSHA should develop, annex, or at least encourage risk-based OELs as the key element of a three-part strategy to solve the "PEL problem"

What do the various kinds of limits ACTUALLY tell the worker who knows what concentration s/he is being exposed to, but wants to know how dangerous it is?

• The OSHA PELs actually indicate levels that lawyers and economists decided were economically feasible for most or all employers to meet! There is lots of cutting-edge risk science in the ***Preambles*** to the PELs, but the numerical limits themselves reflect (anemic) determinations about feasibility. (the word "anemic" in this paragraph is a personal judgment based on my 12 years at OSHA– every other word is, I assert, unimpeachable)

• The ACGIH TLVs indicate levels that very smart, energetic, and creative volunteers together decided met some unknown balance of "reasonable assurance of safety" and reasonable achievability in the workplace. Every such judgment is chemical-specific, not generic.

• At concentrations above or below the PEL or TLV, no knowledge about *how* safe or *how* dangerous is or can be transmitted.

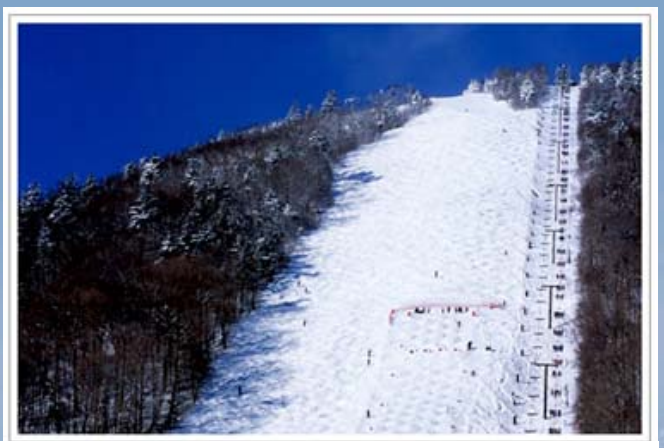
The leaders and rank-and-file of the occupational health world are estranged from risk assessment, and the rift is widening:

- long-standing moral distaste for risk assessment among labor unions, OSHA, NIOSH, etc.;
- tendency to blame risk assessment for delays and failures in the regulatory process;
- belief among many in corporate OHS that risk assessment is "voodoo" (see next slide)
- (mistaken) belief that risk assessment is overly "conservative" (see any of 8-10 articles by AMF on this issue);
- unflatteringly defensive posture ("with us or against us") from the TLV Committee and AIHA;
- rise (esp. internationally) of "control banding" and other qualitative "alternatives" to risk assessment

"Any sufficiently advanced technology is indistinguishable from magic"

-Arthur C. Clarke, 1973 (in *Profiles of the Future*)

If trail signs at ski areas looked like the "new" (proposed) Safety Data Sheet…



"SNORTING ELK"

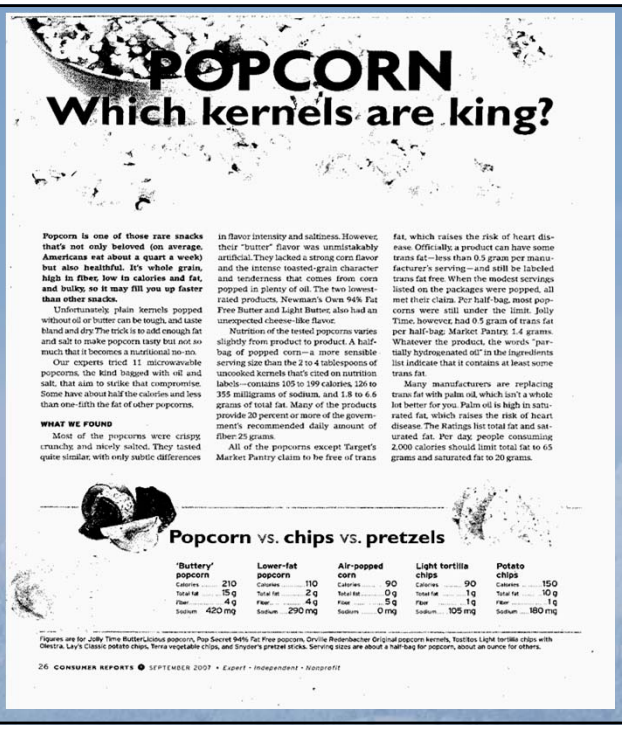
("short" but deadly– maybe length is not a good index for ski trails…)

Principled Objections to Quantifying Occupational Risk (from e-mail to author from a leading industrial hygienist in the UK):

"We have an ethical duty and in most cases a legal duty to explain the risks to health to employees, but I don't believe that we have sufficient information available to quantify the risk even for a group of employees, let alone for an individual.[1] Then there's also an issue about the perception of risk to be considered. We can quantify the risk of dying from smoking, from walking across the street, from traveling in a plane, etc., but do people really consider those estimates of risk in how they live their lives?" [2]

[Answers: 1: nope. 2: yup]

But what about the 150 or so OTHER workers who die each day, from chronic disease due to occupational exposures??



POPCORN
Which kernels are king?

Popcorn is one of those rare snacks that's not only beloved (on average, Americans eat about a quart a week) but also healthful. It's whole grain, high in fiber, low in calories and fat, and bulky, so it may fill you up faster than other snacks.

Unfortunately, plain kernels popped without oil or butter can be tough, and taste bland and dry. The trick is to add enough fat and salt to make popcorn tasty but not so much that it becomes a nutritional no-no.

Our experts tried 11 microwavable popcorns, the kind bagged with oil and salt, that aim to strike that compromise. Some have about half the calories and less than one-fifth the fat of other popcorns.

WHAT WE FOUND

Most of the popcorns were crispy, crunchy, and nicely salted. They tasted quite similar, with only subtle differences in flavor intensity and saltiness. However, their "butter" flavor was unmistakably artificial. They lacked a strong corn flavor and the intense toasted-grain character and tenderness that comes from corn popped in plenty of oil. The two lowest-rated products, Newman's Own 94% Fat Free Butter and Light Butter, also had an unexpected cheese-like flavor.

Nutrition of the tested popcorns varies slightly from product to product. A half-bag of popped corn—a more sensible serving size than the 2 to 4 tablespoons of uncooked kernels that's cited on nutrition labels—contains 105 to 199 calories, 126 to 355 milligrams of sodium, and 1.8 to 6.6 grams of total fat. Many of the products provide 20 percent or more of the government's recommended daily amount of fiber: 25 grams.

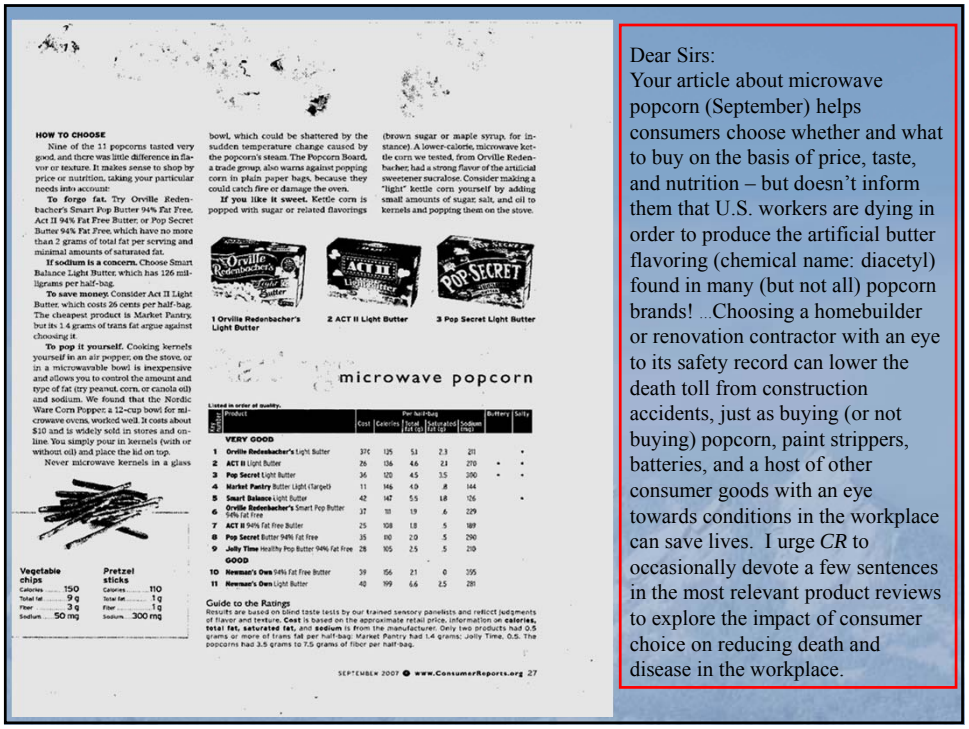
All of the popcorns except Target's Market Pantry claim to be free of trans fat, which raises the risk of heart disease. Officially, a product can have some trans fat—less than 0.5 gram per manufacturer's serving—and still be labeled trans fat free. When the modest servings listed on the packages were popped, all met their claims. Per half-bag, most popcorns were still under the limit. Jolly Time, however, had 0.5 gram of trans fat per half-bag; Market Pantry, 1.4 grams. Whatever the product, the words "partially hydrogenated oil" in the ingredients list indicate that it contains at least some trans fat.

Many manufacturers are replacing trans fat with palm oil, which isn't a whole lot better for you. Palm oil is high in saturated fat, which raises the risk of heart disease. The Ratings list total fat and saturated fat. Per day, people consuming 2,000 calories should limit total fat to 65 grams and saturated fat to 20 grams.

Popcorn vs. chips vs. pretzels

	'Buttery' popcorn	Lower-fat popcorn	Air-popped corn	Light tortilla chips	Potato chips
Calories	210	110	90	90	150
Total fat	15 g	2 g	0 g	1 g	10 g
Fiber	4 g	4 g	5 g	1 g	1 g
Sodium	420 mg	290 mg	0 mg	105 mg	180 mg

Figures are for Jolly Time ButterLicious popcorn, Pop Secret 94% Fat Free popcorn, Orville Redenbacher Original popcorn kernels, Tostitos Light tortilla chips with Olestra, Lay's Classic potato chips, Terra vegetable chips, and Snyder's pretzel sticks. Serving sizes are about a half-bag for popcorn, about an ounce for others.



HOW TO CHOOSE

Nine of the 11 popcorns tasted very good, and there was little difference in flavor or texture. It makes sense to shop by price or nutrition, taking your particular needs into account:

To forgo fat. Try Orville Redenbacher's Smart Pop Butter 94% Fat Free, Act II 94% Fat Free Butter, or Pop Secret Butter 94% Fat Free, which have no more than 2 grams of total fat per serving and minimal amounts of saturated fat.

If sodium is a concern. Choose Smart Balance Light Butter, which has 126 milligrams per half-bag.

To save money. Consider Act II Light Butter, which costs 26 cents per half-bag. The cheapest product is Market Pantry, but its 1.4 grams of trans fat argue against choosing it.

To pop it yourself. Cooking kernels yourself in an air popper, on the stove, or in a microwavable bowl is inexpensive and allows you to control the amount and type of fat (try peanut, corn, or canola oil) and sodium. We found that the Nordic Ware Corn Popper, a 12-cup bowl for microwave ovens, worked well. It costs about $10 and is widely sold in stores and online. You simply pour in kernels (with or without oil) and place the lid on top.

Never microwave kernels in a glass bowl, which could be shattered by the sudden temperature change caused by the popcorn's steam. The Popcorn Board, a trade group, also warns against popping corn in plain paper bags, because they could catch fire or damage the oven.

If you like it sweet. Kettle corn is popped with sugar or related flavorings (brown sugar or maple syrup, for instance). A lower-calorie, microwave kettle corn we tested, from Orville Redenbacher, had a strong flavor of the artificial sweetener sucralose. Consider making a "light" kettle corn yourself by adding small amounts of sugar, salt, and oil to kernels and popping them on the stove.

1 Orville Redenbacher's Light Butter | 2 ACT II Light Butter | 3 Pop Secret Light Butter

microwave popcorn

Listed in order of quality.

Rank	Product	Cost	Calories	Per half-bag: Total fat (g)	Saturated fat (g)	Sodium (mg)	Buttery	Salty
	VERY GOOD							
1	**Orville Redenbacher's** Light Butter	37¢	125	5.1	2.3	211		•
2	**ACT II** Light Butter	26	136	4.6	2.1	270	•	•
3	**Pop Secret** Light Butter	36	120	4.5	3.5	300	•	•
4	**Market Pantry** Butter Light (Target)	11	146	4.9	.8	144		
5	**Smart Balance** Light Butter	42	147	5.5	1.8	126		•
6	**Orville Redenbacher's** Smart Pop Butter 94% Fat Free	37	111	1.9	.6	229		
7	**ACT II** 94% Fat Free Butter	25	108	1.8	.5	189		
8	**Pop Secret** Butter 94% Fat Free	35	110	2.0	.5	290		
9	**Jolly Time** Healthy Pop Butter 94% Fat Free	28	105	2.5	.5	210		
	GOOD							
10	**Newman's Own** 94% Fat Free Butter	39	156	2.1	0	355		
11	**Newman's Own** Light Butter	40	199	6.6	2.5	281		

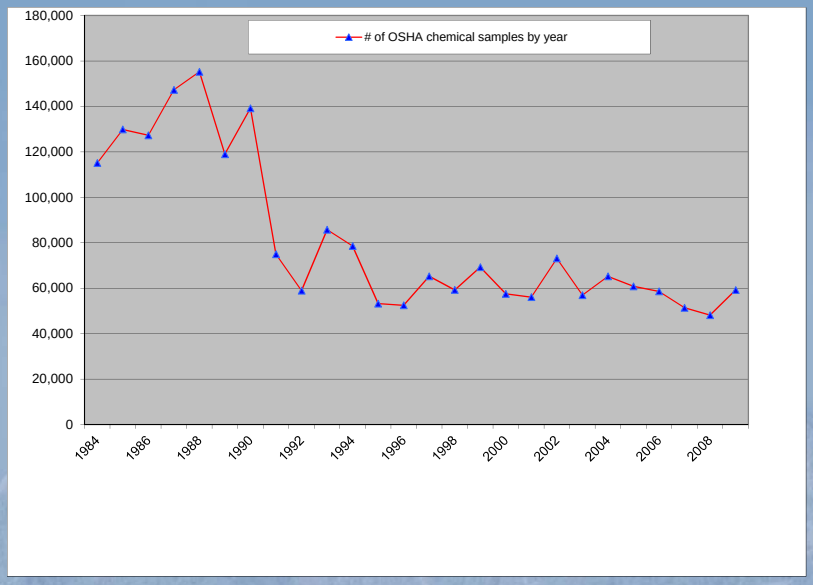
Guide to the Ratings

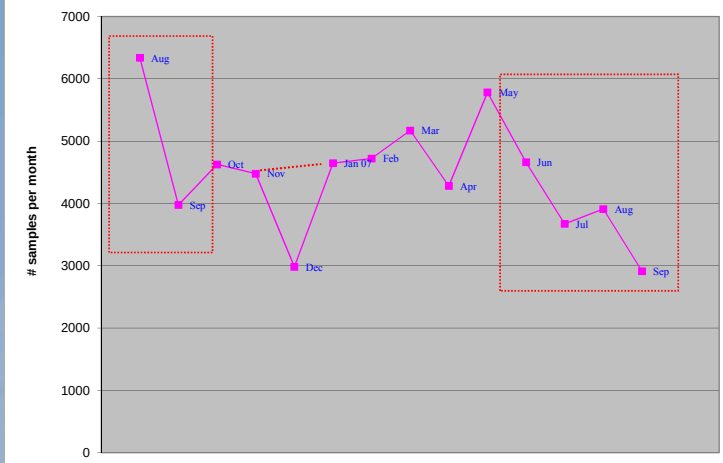
Results are based on blind taste tests by our trained sensory panelists and reflect judgments of flavor and texture. **Cost** is based on the approximate retail price. Information on **calories, total fat, saturated fat,** and **sodium** is from the manufacturer. Only two products had 0.5 grams or more of trans fat per half-bag: Market Pantry had 1.4 grams; Jolly Time, 0.5. The popcorns had 3.5 grams to 7.5 grams of fiber per half-bag.

Vegetable chips
Calories 150
Total fat ..... 9 g
Fiber ..... 3 g
Sodium ..... 50 mg

Pretzel sticks
Calories 110
Total fat ..... 1 g
Fiber ..... 1 g
Sodium ..... 300 mg

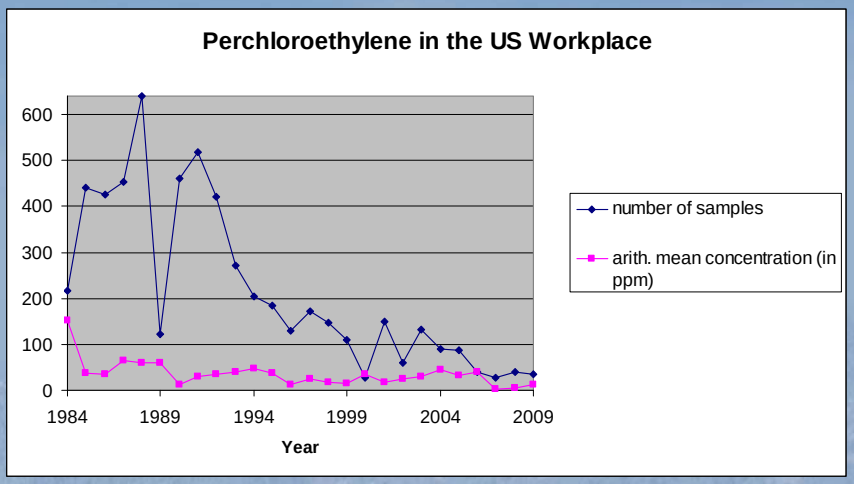
Dear Sirs:
Your article about microwave popcorn (September) helps consumers choose whether and what to buy on the basis of price, taste, and nutrition – but doesn't inform them that U.S. workers are dying in order to produce the artificial butter flavoring (chemical name: diacetyl) found in many (but not all) popcorn brands! ...Choosing a homebuilder or renovation contractor with an eye to its safety record can lower the death toll from construction accidents, just as buying (or not buying) popcorn, paint strippers, batteries, and a host of other consumer goods with an eye towards conditions in the workplace can save lives. I urge *CR* to occasionally devote a few sentences in the most relevant product reviews to explore the impact of consumer choice on reducing death and disease in the workplace.

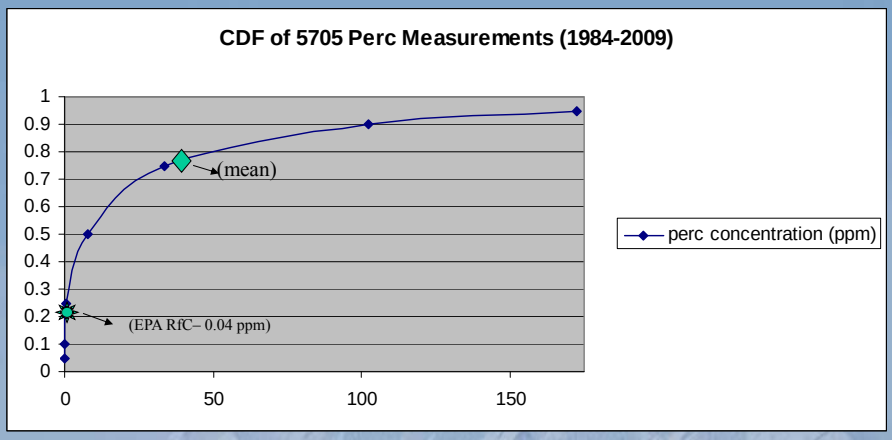




(possible "quota" effect on health inspections each summer as end of FY approaches and "penalty" for doing one health inspection rather than many safety inspections increases)

Trends in OSHA sampling for Perchloroethylene, 1984-2009





(note: EPA's risk assessment for Perc estimates an (adjusted) unit risk factor of about $1x10^{-2}$ per ppm, with pharmacokinetic saturation above 1 ppm)

What might a compendium of approx. 500 risk-based OELs look like?

Concentrations that present an excess lifetime risk of 10^{-3}

~~TABLE Z-1 LIMITS FOR AIR CONTAMINANTS~~

Substance	CAS No. (d)	ppm (a)	mg/m³ (b)
Acetaldehyde	75-07-0	100	180
Acetic acid	64-19-7	10	25
Acetic anhydride	108-24-7	5	
Acetone	67-64-1	750	1800
Acetonitrile	75-05-8	40	70
2-Acetylaminofluorene; see 1910.1014	53-96-3		
Acetylene dichloride; see 1,2-Dichloroethylene			
Acetylene tetrabromide	79-27-6	1	14
Acrolein	107-02-8	0.1	0.25
Acrylamide	79-06-1	0.03	
Acrylonitrile; see 1910.1045	107-13-1		
Aldrin	309-00-2	0.25	
Allyl alcohol	107-18-6	2	5
Allyl chloride	107-05-1	1	3
Allyl glycidyl ether (AGE)	106-92-3	5	22
Allyl propyl disulfide	2179-59-1	2	12
alpha-Alumina Total dust Respirable fraction	1344-28-1		 10 5

The OSHA Permissible Exposure Limits (PELs) are:

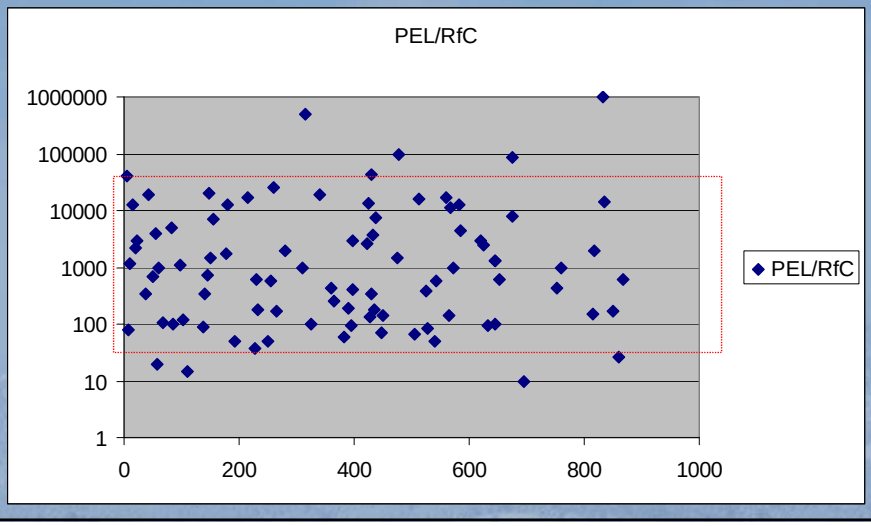
- in roughly 410 ex. 425 instances, "archived" versions of the ACGIH TLVs, frozen in time from 45 years ago;
- in the other 16 cases, set via formal rulemaking– a process, replete with QRA information, in which the science has almost NOTHING to do with the setting of the PEL.

[in the subsequent slides, remember that in every other risk-regulatory arena, we look at the RfC *DIVIDED BY* the legal limit or the prevailing exposures (the "margin of exposure" or "hazard quotient" concepts)]

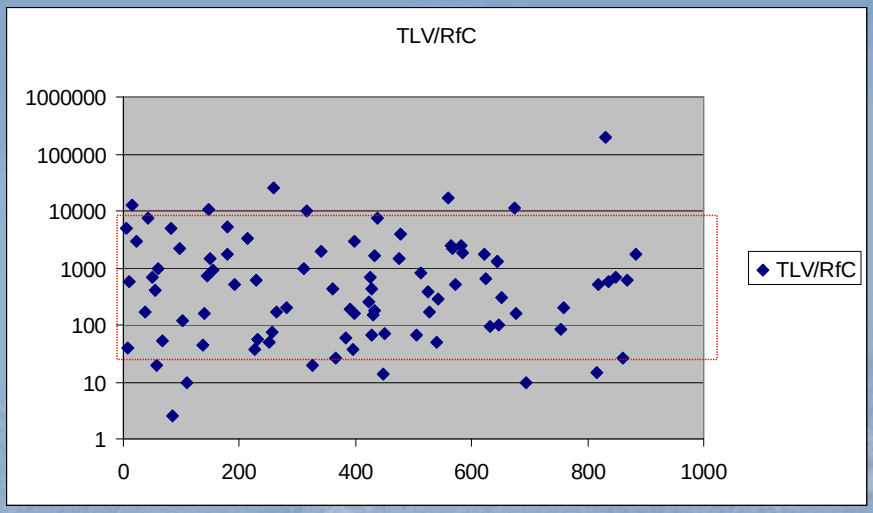
Many of us (see, e.g., Chapter 5 in the NAS **Science and Decisions** report) believe that the "divide by 100 and pray" method of setting non-cancer exposure limits is insufficiently protective. For those substances where humans are truly 10x more sensitive than test animals, and for those humans who are truly 10x more susceptible than the median person, their risk at the NOAEL/100 (the RfC) will be the SAME as the animals' risk at the NOAEL– which is to say, perhaps 5-10 chances **per 100**.

Therefore, exposures 10, 100, 1000 times HIGHER than the RfC may be barbaric.

(most of the PELs are between 50 and 50,000 times the EPA RfC–
a factor of 1000 dispersion about this "gold standard" of non-cancer risk)

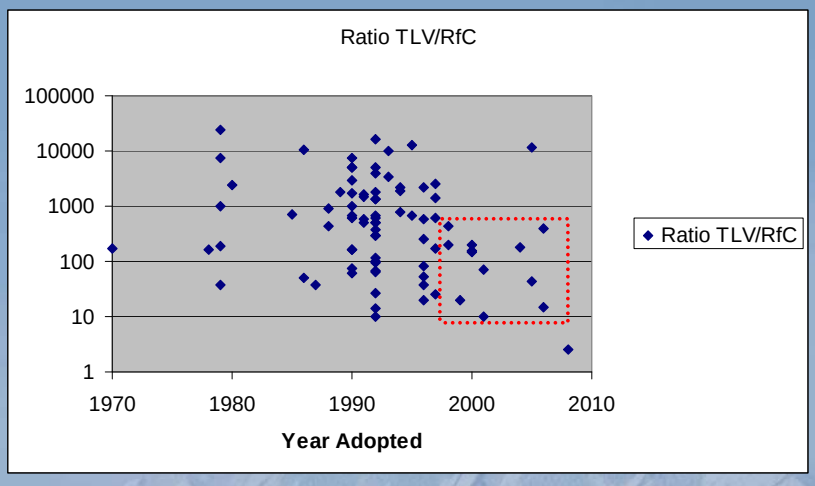


(most of the TLVs are between 20 and 10,000 times the EPA RfC–
a factor of 500 dispersion about this "gold standard" of non-cancer risk)

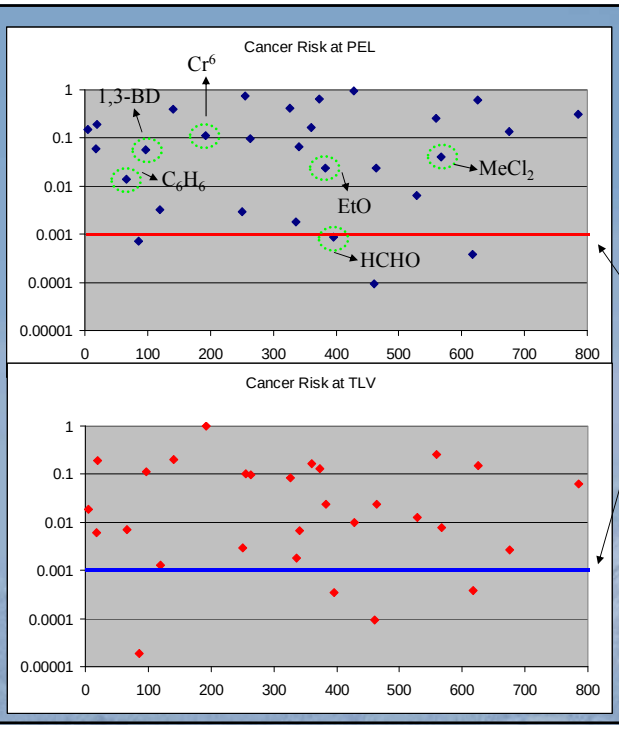


The TLVs are Unrelated to Non-Cancer or Cancer Risk Benchmarks:

	Ratio TLV/RfC (N=91)	Adjusted Cancer Risk at TLV
min.	2.5	4.1×10^{-6}
5th %ile	17	1.8×10^{-5}
25th %ile	84	6.9×10^{-4}
median	500	5.5×10^{-3}
75th %ile	1,770	2.5×10^{-2}
95th %ile	11,040	4.4×10^{-2}
max.	200,000	5.1×10^{-2}
(ratio 95th/5th)	650	2440



- 11 of the most recent 13 TLVs are within 10x to 400x of the RfC (factor of 40 dispersion)
- Of 5 TLVs from 1979, GM (TLV/RfC)= 1060; of 6 TLVs since 2004, GM= 105



Many of us (see, e.g., Chapter 5 in the NAS **Science and Decisions** report) believe that the "divide by 100 and pray" method of setting non-cancer exposure limits is:

- unscientific (assumes population thresholds where the thresholds, if they exist, manifest at the *heterogeneous* individual level);
- a way to stymie sensible cost-benefit decisionmaking (difficult to gauge the value of moving N individuals from "above the line" to "below the line"; impossible to gauge the value of moving individuals from "way above" to "above" or "below" to "way below");
- insufficiently protective (for those substances where humans are truly 10x more sensitive than test animals, and for those humans who are truly 10x more susceptible than the median person, their risk at the NOAEL/100 will be the SAME as the animals' risk at the NOAEL– which is to say, perhaps 5-10 chances **per 100**)

But the process of setting TLVs is even *less* rigorous than this– it is essentially "divide by RAND(x) and pray"

1-Bromopropane: no PEL, TLV=10 ppm

• CDC *Morbidity and Mortality Weekly Report* (12/5/08) published a case report of a 43-year-old man in NJ who had recently begun dry cleaning with "DrySolv"(1-BP)– hospitalized with headaches, fatigue, visual disturbances, twitching, and joint pain– also a PA man hospitalized with ataxia and neuropathy (1-BP levels in his degreasing operation approx. 175 ppm);

• *Journal of Envt'l and Occup'l Medicine* (9/07) reported on 4 furniture workers using 1-BP glue (18 - 254 ppm in air) who developed inability to walk, pain, numbness, vomiting– persisting for up to 8 years after leaving workplace;

• Majersik et al (2007) reported that 6 workers exposed to roughly 100 ppm 1-BP while gluing furniture developed chronic neuropathic pain, persisting for years after leaving their workplaces.

• *European J Endocrinology* (1998) reported on 16 Korean workers using 2-BP who developed primary ovarian failure.

New NTP Cancer Bioassay of 1-BP:

- 18% of female mice exposed to 62.5 ppm developed lung tumors (versus 2% of control mice)
- rare intestinal tumors found in male and female rats
- I calculated the cancer potency factor (linearized multistage model, 95th UCL on linear term) from this bioassay as 1.67×10^{-3} per ppm (45-year, 40 hr/week adjustment)
- (Using identical method, the cancer potency factor for the NTP bioassay of methylene chloride is 1.4×10^{-4} per ppm, a factor of 12 smaller)

From draft ACGIH TLV Basis Document for 1-Bromopropane, 11/18/2010: (note: current TLV is 10 ppm)

- "A TLV-TWA of 0.1 ppm* should provide protection against the potential for neurotoxicity, … in 1-bromopropane exposed workers."
- "A study of 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 (Li et al 2010b)."

My comments: 0.1 ppm is a laudably protective level compared to the current TLV, to EPA's 25 ppm recommendation, and to OSHA's "TSTL"* recommendation, but as a quantitative exercise…

1. Huh?!
2. 1.28 ÷ 10 (LOAEL to NOAEL) ÷ 10 (intraspecies susceptibility) = 0.013 ppm
3. By my analysis of the new 1-BP cancer bioassay, 10^{-4} excess cancer risk level = 0.06 ppm

* ("the sky's the limit")

A Not-Atypical Rationale for TLV Selection:
(Isopropanol, 2003)

The TLV is set on the basis of avoidance of ocular and upper respiratory tract irritation. Few human studies have been completed and sample sizes were relatively small; available human studies have suggested a LOAEL of 400 ppm resulting in mild irritation of the eyes, nose, and throat or subtle changes in postural sway… The lowest chronic NOAEL in rodents is 500 ppm. The lowest applicable subchronic LOAEL in rodents is 500 ppm, based on obvious upper respiratory tract irritation, with a NOAEL of 100 ppm.

A TLV–TWA of 200 ppm and a STEL of 400 ppm are recommended for isopropanol. The TLV–TWA recommendations should minimize the potential for objective narcotic effects, significant irritation of the eyes or upper respiratory tract, or systemic toxicity.

Other recent TLV "rationales":

- insoluble Cr^{6} componds (2004)– TLV of 10 ug/m^3– although a cancer risk assessment suggested a 10^{-4} excess lifetime risk level would instead be 0.008 ug/m^3 (1/1250th of the TLV), this calculation may be "seriously in error" (note– OSHA risk assessment in 2006 estimated a risk of about $4x10^{-5}$ at 0.008 ug/m^3…)
- acetaldehyde (2011)– ceiling of 25 ppm, because "irritation occurs at levels much below concentrations that have been shown to cause long-term effects"– except for the implications of the adenocarcinomas in rats at 750 ppm…
- hydrogen fluoride (2005)– TLV of 0.5 ppm, although irritation and lavage fluid changes documented at 1-3 ppm
- TDI (2003)– TLV of 5 ppb, although FEV_1 of those exposed > 3.5 ppb was reduced by an average of 200 ml…

Six WEELs Released for Public Review March-May 2011:

- 1/20 of a LOAEL that "will be a NOAEL";
- ½ of a frank effect level;
- 1/10 of a frank effect level;
- 1/3 of a frank effect level;
- 1/70th of a NOAEL (**now** we're talkin'…)
- 1/3 of (4-week) NOAEL

Common Misconceptions About (and Distortions of) the NAS "Silver Book" (*Science and Decisions: Advancing Risk Assessment)*

- we recommended that EPA (and other agencies) treat all adverse human health effects as always obeying a straight-line dose-response function, from the highest laboratory dose down to zero;
- we urged EPA to retain its current "default" assumptions used in risk assessment, and to resist departing from them in favor of new information;
- we want political managers to dictate how risk and cost-benefit analyses will be conducted.

TABLE 6-3 Examples of "Missing" Defaults in EPA "Default" Dose-Response Assessments

- *For low-dose linear agents, all humans are equally susceptible during the same life stage* (when estimates are based on animal bioassay data) (EPA 2005a). The agency assumes that the linear extrapolation procedure accounts for human variation (explained in Chapter 5), but does not formally account for human variation in predicting risk. For low-dose nonlinear agents, an RfD is derived with an uncertainty factor for interhuman variability of 1-10 (EPA 2004a, p. 44; EPA 2005a, p. 3-24).
- *Tumor incidence from conventional chronic rodent studies is treated as representative of the effect of lifetime human exposures after species dose equivalence adjustments* (EPA 2005a). For chemicals established as operating by a mutagenic mode of action, that holds after adjustment for early-life sensitivity (EPA 2005b). This assumes (1) that humans and rodents have the same "biologic clock," that is, that rodents and humans exposed for a lifetime to the same (species-corrected) dose will have the same cancer risk, and (2) that a chronic rodent bioassay, which doses only in adulthood and misses late old age (EPA 2002a, p. 41), is representative of a lifetime of rodent exposure.
- *Agents have no in utero carcinogenic activity.* Although the agency notes that in utero activity is a concern, default approaches do not take carcinogenic activity from in utero exposure into account, and risks from in utero exposure are not calculated (EPA 2005b; EPA 2006a, p. 29).
- *For known or likely carcinogens not established as mutagens, there is no difference in susceptibility at different ages* (EPA 2005b).
- *Nonlinear carcinogens and noncarcinogens act independently of background exposures and host susceptibility* (see Chapter 5 for full discussion).
- *Chemicals that lack both adequate epidemiologic and animal bioassay data are treated as though they pose no risk of cancer worthy of regulatory attention*, with few exceptions. They are typically classified as having "inadequate information to assess carcinogenic potential" (EPA 2005a, Section 2.5); consequently, no cancer dose-response assessment is performed (EPA 2005a, p. 3-2). Integrated Risk Information System and provisional peer-reviewed toxicity values are then based on noncancer end points, and cancer risk estimates are not presented.

Example Risk-Based OEL for a Carcinogen (Perchloroethylene):

- linear term of multistage dose-response polynomial = 1.46×10^{-3} per ppm (upper 95th percentile)
- adjust by (10/20 m^3/day) (5/7 days) (45/70 yr) = 3.35×10^{-4} per ppm
- Therefore, **2.98 ppm** corresponds to an excess cancer risk of 10^{-3}
- [note: PEL= 100 ppm; TLV = 25 ppm; new Philadelphia limit (residential neighbors) = 40 ppb]

Recommended Default for Interindividual Variability in Cancer Susceptibility

An assumption that the distribution is lognormal is reasonable, as is an assumption of a difference of a factor of 10-50 between median and upper 95th percentile people, as indicated by the series of examples provided in Chapter 4. It is clear that the difference is significantly greater than a factor of 1, the current implicit assumption in cancer risk assessment. In the absence of further research leading to more accurate distributional values or 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 for the low-dose linear case, as would be a default lognormal distribution. A factor of twenty-five could be interpreted as a factor of 10 for pharmacokinetic variability, and a factor of 2.5 for pharmacodynamic variability.

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: For a lognormal distribution, the mean to median ratio is equal to $\exp(\sigma^2/2)$. When the 95th percentile to median ratio is 25, σ is 1.96 [=ln(25)/1.645], and the mean exceeds the median 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.

Thus under this new default, the value for the median person would remain as provided by the current approach to cancer risk assessment; for a default of a factor of 25, the average would be higher by a factor of 6.8. It would be important for the cancer risk assessment to express interindividual variability by showing the median and average population risks, as well as the range of individual risks for risk-management consideration.

Science and Decisions: Advancing Risk Assessment
http://www.nap.edu/catalog/12209.html

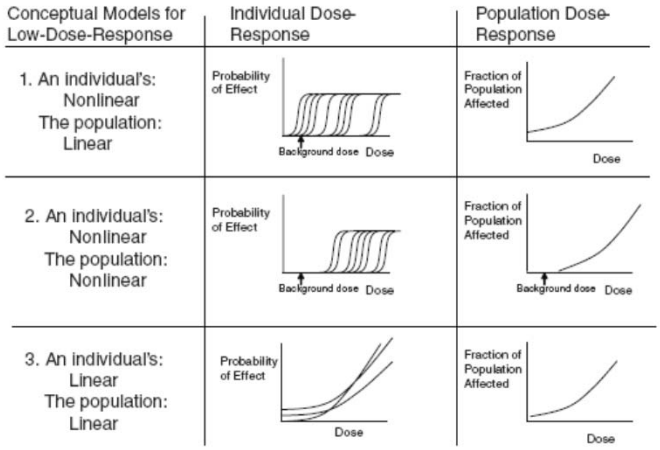


FIGURE 5-10 Examples of conceptual models to describe individual and population dose-response relationships.

FIGURE 5-5 Nonlinear or threshold low-dose response relationships for individuals and populations.

3. *Low-dose linear individual and population dose-response.* For this conceptual model, both individual risk and population risk have no threshold and are linear at low doses, as illustrated in Figure 5-6. Note that *low-dose linear* means that at low doses "added risk" (above background) increases linearly with increasing dose; it does not mean that the dose-response relationship is linear throughout the dose range between zero dose and high doses.

Example Risk-Based OEL for a Non-Carcinogen (Phosgene)
[*adapted from Box 5-2 of* ***Science and Decisions,*** NAS 2009]:

- 0.2 ppm is LOAEL for bronchiolar fibrosis in rats (12 weeks);
- EPA calculated BMD_{10} = 0.1 ppm (=170 μg/m^3)
- $BMDL_{10}$= 0.018 ppm (=30 μg/m^3)
- RfC = 30 ÷ 10 ÷ 10 = 0.3 μg/m^3

NAS method:

- 170 ÷ 2 (subchronic-chronic) = 85 μg/m^3
- x (20/10)(7/5)(70/45) = 370 μg/m^3
- $\sigma_{\text{animal BMD}}$ = log(170/30) ÷ 1.645 = 0.46
- $\sigma_{\text{A-H pharmacodynamics}}$= 0.42
- $\sigma_{\text{subchron-chron}}$= 0.34
- $\sigma^2_{\text{human}} = 0.46^2 + 0.42^2 + 0.34^2 = 0.5036$; therefore $\sigma_{\text{human}} = 0.71$
- lower bound on BMD_{10} = 370 ÷ $10^{(1.645)(0.71)}$ = 25 μg/m^3
- therefore, 10^{-3} risk level = 25 ÷ (0.1/0.001) = ***0.25 μg/m^3***
- Note: TLV currently set at 400 μg/m^3

Categories of Uses for Risk-Based OELs:

- the right to know;
- inputs to probability-of-causation estimates;
- common metric for making purchasing decisions among substitute products, inputs;
- vehicle for company self-congratulation;
- inputs to doing life-cycle analyses or corporate sustainability metrics *properly;* and perhaps
- occasional enforcement by OSHA (see next slides)

General Duty Authority Enforcement:

NOT the Center for Progressive Reform recommendation (cite first-instance for substances with TLVs but no PELs),

but: (1) create or annex risk-based OELs
(2) document via inspection an exceedance of OEL
(3) identify feasible means of controlling to OEL
(4) thereby establish employer's general duty to control to OEL upon *subsequent* inspection(s)

This would be labor-intensive, slow, incremental progress towards reducing occupational exposures– in other words,

vastly better than nothing.

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%]

Conclusion:

We have not “evolved beyond” the need to assess, communicate, and reduce risk: modern scientific methods are SLIGHTLY more complicated than control banding and other qualitative measures, and HUGELY more informative, useful, efficient, and responsive to the reasonable expectations of Congress, the courts, and the public.