

HIGHLIGHTS OF TESTIMONY by
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OSHA RULEMAKING HEARING ON MODIFICATIONS
TO THE HAZARD COMMUNICATION STANDARD (“HazCom”)

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Issue:

- For the past 27 years, OSHA has required manufacturers and users of hazardous chemicals to include on the “Material Safety Data Sheet” (MSDS) various recommended occupational exposure limits (OELs), including the Threshold Limit Values (TLVs) established by the American Council of Governmental Industrial Hygienists (ACGIH) and the Permissible Exposure Limits (PELs) set by OSHA itself. Among various changes purported to make the HazCom standard more closely track the United Nations’ “Globally Harmonized System of Classification and Labeling of Chemicals,” OSHA now proposes to make only the disclosure of the PELs mandatory, and to make all other national and international exposure limits voluntary to disclose to workers and other users of the substance.
- Apparently OSHA was pressured to propose removal of the TLVs by various industry groups, who argue that the TLVs are not set via a transparent and fully scientific process.
- This change will deprive purchasers of chemicals and the workers they employ of crucial health hazard information, leaving only the OSHA PELs, which (see below) are *not* useful for hazard communication. This assertion may be jarring, but having worked on all of the PELs promulgated since the mid-1990s, I know first-hand it is true. Moreover, this change will not contribute to global harmonization (and there are many aspects of the revised HazCom standard that will not match those of other countries anyway): contrary to OSHA’s assertion in the proposal that the current system requires “a list of U.S.-specific OELs that must be included,” many other countries rely on the TLVs. For example, the European Agency for Safety and Health at Work states that “ACGIH-TLVs and the criteria documents are a very common base for setting [exposure limits] in the USA and in many other countries.”

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Analysis:

- My colleague Sidney Shapiro (University Distinguished Professor of Law, Wake Forest University) will testify immediately before my remarks, and will thoroughly refute any legal argument against OSHA's right to require disclosure of the TLVs (and other national and international OELs) on the chemical data sheets.
- My testimony will then make three fundamental scientific points and one policy point:
 1. More than 410 of the roughly 425 OSHA PELs (nearly 97 percent of them) are *themselves* TLVs! OSHA incorporated these TLVs by reference when the Agency was founded in 1970 (the values themselves date from 1968 or earlier), and the Agency has been successful in setting newer OELs in only 16 cases since then. *If companies should not be required to disclose the TLVs because they are controversial or "unscientific," it makes absolutely no sense to prefer the OSHA PELs to them, as in 97 percent of the cases the PELs are simply "archaic TLVs," set via a process that was far less transparent at the time and that 40 or more years of scientific progress has passed by.* The only logical, if self-serving, reason to argue for disclosing the PELs and suppressing the TLVs is that in virtually all cases, the TLVs are **lower (more worker-protective)** than the PELs. This may be good business, but it is junk science (see #3 below).
 2. In more than 200 other cases, ACGIH has since developed TLVs for substances that had no TLV in 1968, and hence have no OSHA PEL whatsoever today. Earlier today, a witness (W. Caffey Norman) representing the Halogenated Solvents Industry Alliance showed a compelling example of how relying only on the respective PELs could mislead prospective purchasers of similar substances (and the workers they employ) into making deadly choices. Methylene chloride is one of the 16 substances with a "new" OSHA PEL (25 ppm, set in 1997). A substitute chemical, *n*-propyl bromide (a.k.a. 1-bromopropane), has no OSHA PEL, but a TLV of 10 ppm. Disclosing only the PEL would make it appear that *n*-propyl bromide is safer than methylene chloride, whereas the data clearly show that the opposite is true (the brominated material is a more potent neurotoxin, and I recently analyzed data from a new cancer bioassay that suggests it is roughly four times more potent a carcinogen).
 3. I have been a pioneer in advancing the field of quantitative risk assessment for more than 25 years. *Although the Preamble texts of the PEL regulations promulgated since 1970 synthesize an enormous amount of cutting-edge risk science information, the PEL number itself is NOT risk-based: it instead is set*

*entirely based on an economic/political determination of what concentration U.S. companies can readily achieve in their establishments. Although (see “Alternative Recommendation” section below) I fault the TLVs for not being as risk-based as I think OELs should be, **they are nonetheless vastly more science-based than the PELs, simply because they do not subordinate the science to a highly subjective economic judgment.***

Two aspects of setting PELs make risk less and less relevant. First, any value across a wide range of concentrations (and hence a wide range of risk levels) can generally be deemed “infeasible,” and the (subjective) infeasibility determination trumps any concern about risk. That range then becomes wider still because OSHA generally *chooses* to set a single PEL for each substance even though some industry sectors could clearly achieve lower, but still significantly risky levels. For example, OSHA analyzed feasibility for 36 different industries in the 2006 hexavalent chromium standard—some industries (e.g., chromium dye producers) would have had to put 40% of their workers in respirators even at a PEL of 20 $\mu\text{g}/\text{m}^3$, whereas many other industries could clearly have complied with a PEL of 0.25 $\mu\text{g}/\text{m}^3$. The final standard of 5 $\mu\text{g}/\text{m}^3$ is closer to the high end of this range than to the low end, but more importantly, it is 10 to 45 times higher than the highest possible risk level (1 chance in 1,000) the Supreme Court said was acceptable, so it was clearly not chosen on risk grounds—rather, it was DOL’s idea of what was feasible. Therefore, a purchaser or worker who reads an SDS and sees only the 5 $\mu\text{g}/\text{m}^3$ number learns nothing about how dangerous chromium is, nor can s/he even assume that at least it is less dangerous than a substitute material with a PEL of 1 $\mu\text{g}/\text{m}^3$ —chromium is both intolerably risky at 0.5 $\mu\text{g}/\text{m}^3$ and can feasibly be reduced to 0.5 in many places, but OSHA judged that everyone could settle for 5 because (purportedly) some establishments could control no lower. *This has nothing to do with chemical hazard communication: this is “chemical cost communication” masquerading as science or risk.*

In my testimony, I will summarize several analyses I recently undertook showing that the TLVs (especially the most recent ones) adhere much more closely to a common risk-based benchmark than the PELs, which are “all over the map” in terms of risk. I will also make two analogies to explain the folly of trying to inform workers via the PELs. As the images below suggest, a nutrition label containing “PEL-type” information instead of the TLV would be farcical (it would tell the consumer how much of the *cost* of a Twinkie is attributable to its fat content, not whether that amount of fat is harmless or harmful); a trail sign at a ski area based on OSHA’s proposed logic would send beginning skiers down the “green” trail, which is shorter (!) than the alternatives but frighteningly steep:

Nutrition Facts	
Serving Size 1 Twinkie (148g/5.3oz)	
Amount Per Serving	
Calories 100	Calories from Fat 81
	% of production cost
Total Fat 9g	19%
Saturated Fat 0g	0%
Cholesterol 0mg	0%
Sodium 0mg	0%
Potassium 720mg	21%
Total Carbohydrate 26g	9%
Dietary Fiber 3g	12%
Sugars 3g	39%
Protein 4g	
Vitamin A 0% • Vitamin C 45%	
Calcium 2% • Iron 6%	
Thiamin 8% • Riboflavin 2%	
Niacin 8% • Vitamin B ₆ 10%	
Folate 6% • Phosphorous 6%	
Zinc 2% • Magnesium 6%	



- The concern about “self-incrimination” from having to report TLVs with which the manufacturer or user does not agree is disingenuous, because the opponents of the TLVs (with OSHA’s passive acquiescence) have been able to manipulate the data sheets to portray their views about the substance’s hazards despite the mandatory elements. The required elements can be satisfied in a few words or a sentence, and then the author of the data sheet can surround any unwanted information with as much contradictory “spin” as s/he wants, whether or not the additional information is correct. In my testimony, I will quote from the data sheet from one of the major manufacturers of methylene chloride. It includes the required admission that the solvent causes malignant tumors in laboratory animals, but goes on to claim that these tumors are irrelevant to humans and that the chemical is not a human carcinogen—this despite the fact that the manufacturers attempted to make the same scientific arguments during the 1997 OSHA rulemaking, and the overwhelming consensus of independent peer reviewers was that the claims were premature at best and fallacious at worst. If a manufacturer wanted to surround a TLV s/he thought was “too low” with a forest of caveats, OSHA would turn a blind eye, which suggests to me that the opponents of the TLVs don’t even want to be bothered to express their own perspective on the risk. The dichotomy between “right to know” and “ignorance is bliss” is quite stark in this situation, and suppressing science-based OELs reflects the latter pathway.

An Alternative Recommendation—“Federal TLVs”:

Although the TLVs are much more faithful to the underlying risk information than the PELs are, neither set of OELs is ideal for expressing relative and absolute hazard information to workers. I urge OSHA (with substantial participation from NIOSH, if it is willing) to develop its own set of risk-based OELs—having done so, I would eventually see no need to continue to require that the TLVs be listed on the data sheets. In my opinion as a risk assessor and former Director of Health Standards for OSHA, “risk-based exposure goals” (RBEGs) for roughly 150 of the most important substances could be developed by a small group (fewer than 10) of trained OSHA staff, working part-time on this for no more than 3 years. Indeed, the California EPA hired a single contractor in 2007 who developed approximately 50 OELs for carcinogens, chronic toxicants, and developmental toxins, reportedly for less than \$50,000.

I proposed exactly this project to the OSHA Assistant Secretary in 1999, who quickly dismissed it on the grounds that “he was put here to regulate” (we all know how well that worked out...). I agree that it is more urgent to fix the broken PEL process (and will be presenting along with PEER recommendations to that effect shortly) than to develop non-binding informational values, but it is highly short-sighted to see these complementary activities as either/or. The main reason it takes so long to set a PEL is the difficulty of conducting economic feasibility analyses, and OSHA’s lack of competence in this area—and as I have shown, this very analysis then renders the PEL useless for communicating risk information.

Risk assessors at OSHA and NIOSH are perfectly capable of adapting existing cancer potency factors (adjusted for the differences between continuous exposure for a 70-year lifetime and 40 hr./wk. occupational exposure for 45 working years) to derive concentrations that would increase individual cancer risk by 10^{-4} (personally, I would suggest RBEGs for carcinogens be set at this level, even though this might be a stretch goal for some substances). Similarly, they could either derive reference concentrations (for the sake of argument, perhaps pegged to the No Observed Adverse Effect Level divided by 10), or, following the lead of the recent National Academy of Sciences recommendations, estimate risk for non-carcinogens probabilistically (**Science and Decisions: Advancing Risk Assessment**, Chapter 5). I would recommend that OSHA engage stakeholders from labor, industry, and academia in an attempt to reach consensus on the appropriate *general science-policy principles* for conducting such analyses, but if those discussions break down (as they did in the late 1990s around the PEL process), to forge ahead.