

September 29, 2008

Leon R. Sequeira
Assistant Secretary for Policy
U.S. Department of Labor
200 Constitution Avenue, NW, S-2312
Washington, DC 20210

SUBJECT: Risk Assessment Policy
RIN: 1290-AA23

Dear Assistant Secretary Sequeira:

I read with great interest the Department of Labor's August 29 proposal (73 FR 50909-50915) to add material to 29 CFR Part 2 that relates to the conduct and methodology of quantitative risk assessment (QRA). I have for the past 25 years been an unwavering supporter of QRA, and as OSHA's Director of Health Standards Programs from 1995-2000, led the effort to produce QRAs for 1,3-butadiene, methylene chloride, hexavalent chromium, six "PEL Update" substances, tuberculosis, assigned protection factors for respirators, and other assessments that have (and in some cases, have not) resulted in OSHA final health standards.

Indeed, I testified in my official capacity and on behalf of OSHA before the Presidential/Congressional Commission on Risk Assessment and Management in 1995, and I was the one who made the recommendation, adopted by the Commission, that "OSHA should publish, after appropriate public involvement and review, one or more sets of guidelines that lay out its scientific and policy defaults." At that time, I had recently finished serving for three years on a National Academy of Sciences committee (*Science and Judgment in Risk Assessment*) that urged EPA to improve its existing risk assessment guidelines. I wrote a major portion of that report (including an authored minority report in Appendix N) discussing the need for risk regulatory agencies to publish their science-policy defaults, to articulate a philosophy for whether and when defaults should be modified, and to publish detailed scientific criteria giving researchers a signal of what type and quality of data would be necessary for such modification, in light of the need to update the science but also to avoid costly errors of risk underestimation and the resultant needless toll of disease and death. I was recently named to the current NAS committee that is conducting a 25th-

anniversary review of the original 1983 “Red Book” for risk assessment, and although our draft final report is confidential at this writing, it will also contain major sections on defaults and risk assessment guidelines. I believe I write with considerable authority about what would make risk assessment guidelines wise or unwise, sound or unsound, and legally proper or improper.

Even more specifically, I wrote, with considerable help from several OSHA staff (at least one of whom is currently active at the Agency, as an Office Director in Standards and Guidance) and a university-based expert contractor, a detailed set of *OSHA risk assessment guidelines* in 1999. It was my intention as Director of Health Standards to vet these guidelines through a series of public meetings, and to publish them as an OSHA Directive, so that they could be updated and modified easily—just as EPA has done numerous times with its various risk-related guidance documents, *none of which* has been codified in the CFR. Because of a policy decision by the Assistant Secretary for OSHA at that time to concentrate exclusively on ergonomics from 1999 until the end of the Clinton administration, these guidelines were never finalized. However, I am confident that paper and electronic copies of this document remain at OSHA headquarters, and urge DOL to review this document carefully before deciding whether and how to proceed with the NPRM issued in August.

I strongly support the concept that OSHA (and MSHA) should publish risk assessment guidelines. ***But the document published in the Federal Register bears no resemblance whatsoever to risk assessment guidelines, and is in no way responsive to the recommendations of scientific bodies and OMB in this regard.*** Quantity does not necessarily mean quality, but in light of the fact that the draft risk assessment guidelines we wrote in 1999 covered 145 manuscript pages¹, and that the 1980 OSHA “Cancer Policy” covered 294 Federal Register pages (for a document entirely about the Hazard Identification step of risk assessment, with nothing to say about dose-response quantification, exposure assessment, or risk characterization), how can DOL possibly advertise a regulatory text that fills *less than one Federal Register page* as something that “explain[s] the agency’s existing best practices related to risk assessment in one easy-to-reference regulation”?? It does nothing of the sort.

Rather, the relevant portions of the Federal Register contain less information than a magazine advertisement about a car would contain about how to build the automobile itself.

¹ And if press accounts of a \$300,000 contract let to produce the 2008 document are correct, I hasten to add that the 1999 document was produced at roughly one-tenth this cost.

There is not a single statement of risk assessment science or science-policy in the document. Not a single default assumption is codified, nor is there any explanation whatever of when and how OSHA and MSHA might determine that new information renders an old default implausible or unwise. Instead, we are told (FR page 50911) that “the [dose-response assessment] process generally involves: Selection of suitable study data, exposure metrics, and health endpoints; selection and application of appropriate risk models to the data,” and that (p. 50912) “exposure parameters include the level, duration, route, and frequency of exposure.” It is as if DOL was offering to the Patent Office a wonderful new invention it called an “automobile,” and described it only as “a product that contains metal, rubber, and plastic, and that when built will transport passengers at speeds of up to 100 mph.” HOW will DOL agencies select “suitable study data”? How will they estimate the level and duration of exposure? What risk models are “appropriate,” and how will we know they are? (Later in these comments I provide a longer, but still quite incomplete, list of the sorts of questions this guidance document should have posed and answered). A collection of jargon (not always used properly, even so) and buzzwords *about* risk assessment is not risk assessment.

An aimless, “case-by-case” approach to risk assessment, coupled with this useless document purporting to provide guidance, would all be very worrisome if DOL had presented a single shred of evidence that without such “guidance,” previous OSHA risk assessments were deficient *in any respect whatsoever*. But although these assessments (as any risk assessment could, almost by definition) have been improved (and having written several of them, I know they could have been, but having defended several of them for OSHA in court I see no reason to elaborate here), OSHA has in fact produced several state-of-the-art risk assessments that were models of transparency, clarity, and the use of sophisticated science. All the current document does is add a dilatory step (the ANPRM) without justifying the need for additional process. It certainly does not “compile, in one easy-to-reference regulation, all of the Department’s existing best practices related to risk assessment” (FR, page 50910), as it utterly fails to discuss roughly 95% of the details of an OSHA risk assessment that the Agency *already* has “practices” for (which may or may not deserve being called “best”—the proposal is simply silent).

It is a cornerstone of administrative law that Agency action can be overturned as arbitrary and capricious if the agency has “entirely failed to consider an important aspect of the problem” (see, e.g., *MVMA v. State Farm*, 1983). DOL’s attempt to add a new subpart 2.9 to 29 CFR governing “assessment of occupational health risks,” but failing to mention the vast majority of science and science-policy issues involved in occupational health risk assessment (and resolving not a single one of these issues whatsoever), *is a textbook example of an arbitrary and capricious failure to consider many important aspects of the problem at issue.*

If DOL is determined to add the ANPRM step to the process, then it should either withdraw this proposal and restart the initiative to craft true risk assessment guidelines that was begun and suspended under the Clinton Administration (adding the ANPRM step as part of a real guidance document), or else publish the simple ball-and-chain of the ANPRM requirement (along with the improvements to the electronic docket, about which I defer to the comments of others who have already submitted) in a form that does not falsely advertise itself as “Requirements for DOL Agencies’ Assessment of Occupational Health Risks,” which the current document assuredly is not an example of.

If DOL choose to follow the latter course, I offer only this policy-driven comment:

The current political leadership of the Department has not seen fit to conduct a single occupational health risk assessment on its own volition since coming to office in January 2001.² Having done no risk assessment, and having nevertheless determined that future risk assessments should be done even more slowly, it should have the decency to produce a single product before constraining the activities of future officials who might someday wish to produce one.

As for the substance of an ANPRM, I offer this from my experience directing OSHA rulemakings: OSHA is quite competent at gathering all of the published literature about risks and control costs at the earliest stage of pre-rulemaking, and its stakeholders are quite capable of

² The 2006 hexavalent chromium rule, of course, was only produced because of a court order, and the risk assessment contained therein was very similar to one we had produced in 1998-99. In any event, the risk assessment had no bearing on the final PEL, which was chosen purportedly as the “lowest feasible limit” despite allowing cancer risks 10 to 45 times higher than the highest possible boundary of unacceptable risk set by the Supreme Court in 1980.

providing both redundant (published) and useful unpublished information to the Agency at the first sign of regulatory interest (informal discussions OSHA always has with its stakeholders, coupled with the signals sent in the Regulatory Agenda semiannually). But even more importantly, in my experience when OSHA has been “surprised” by new information coming over the proverbial transom, it happens *late* in the process, precisely because interested parties benefit (or believe they will benefit) by holding this information back until it suits their purpose! In the methylene chloride rulemaking I directed, for example, we received only weeks before sending to OMB the draft final rule a collection of in-press manuscripts from the Halogenated Solvents Industry Alliance, with a cover note from a lobbying firm HSIA retained explaining that these articles would “prove” that the cancers found in various studies of animals exposed to methylene chloride were biologically irrelevant to humans. We delayed promulgation for nearly a year while reopening the record to admit public and expert comment on these studies. The expert comments were overwhelmingly derisive, generally referring to the articles as unworthy of publication, but I regard the decision to reopen the record as proper despite the outcome and the cost to exposed workers. The point is that adding a step at the beginning of the rulemaking process does little if anything to increase the quantity of meritorious information, and only gives mischief-makers the chance to try to *further* delay a less timely rule.

The requirement (FR, page 50914) that “the strength or weakness of any data received [from the ANPRM] shall be carefully evaluated by agency scientists and experts in the same manner that comments in response to an NPRM are reviewed” betrays the true intent of the proposal—to force OSHA and MSHA to undergo two completely redundant “turns of the wheel” before sending a draft final rule to OMB for its review. *I challenge DOL to provide even a single example of an OSHA risk assessment produced subsequent to the 1980 Benzene decision where explaining the Agency’s position twice would have improved the process or changed the outcome.* I further challenge DOL to provide even a single example of a study, database, or article that OSHA had not already considered in an NPRM—that is, information that it would not

have obtained without an ANPRM.³ If DOL cannot justify the need for an ANPRM using historical evidence, I believe a reviewing court would waste little time in invalidating this rule.

In other words, it is possible that an Agency (and an agency's stakeholders) less adept than OSHA at *finding* useful data might benefit from a formal preliminary round of information-gathering, but a requirement to respond to comments both before and after publishing the NPRM has no value-added, at least none justified in the August notice. The irony—if that is the right word—of DOL seeking to graft onto the process the very step that it failed to take in August (that is, publishing it as an NPRM rather than an ANPRM!) will, I suspect, be of great interest to the reviewing court if this action is not withdrawn.

Questions for the Department:

Based on a review of the 1999 internal OSHA document where risk assessment guidelines were drafted, along with my extensive experience in QRA, I request that DOL answer these questions before proceeding with this rulemaking. There are *many* more questions that OSHA already asked and answered in the 1999 draft risk assessment guidelines document, and many other questions that EPA and other agencies have tackled that the 1999 document did not, but this is a sampling of the kinds of information that would have to be present in order to even begin to “compile in one place the Department’s best practices with respect to risk assessment.”

By focusing on these issues that the proposal ignores, I do not mean to imply that there are not also many instances of unscientific and incorrect language in the few places where the proposal *does* attempt specificity. Just to give one of many, DOL proposes to require (pp. 50911-12) that its agencies support the choice of input parameters whenever they use a “physiologically based model.” DOL is presumably attempting to draw a contrast between default interspecies extrapolation procedures that use allometric scaling rules (such as body weight to the 2/3 or 3/4 power) and substance-specific procedures that use physiologically-based pharmacokinetic (PBPK) models—but PBPK is the correct term, and DOL seems to be unaware

³ Needless to say, information that only was generated during or after the proposal’s comment period would not be an example that meets this challenge, nor would information that was closely held until an interested party saw fit to spring it upon the process at a later date.

that the allometric models (i.e., those which do not rely on “input parameters”) are all based on physiological theory and evidence.⁴

I realize that the August notice only solicits comment on the ANPRM and the e-docket provisions, but I recognize no legal authority for the Department to amend the CFR (as opposed to publishing guidance) while trying to limit public comment only to portions of the changes.⁵ If DOL wishes to change its “internal procedures” (and wishes to perpetuate the bizarre claim that these incomplete and unscientific risk assessment guidelines do not affect regulated entities and workers), then it should issue a Directive. I cannot believe that the APA contemplated agencies encumbering the CFR with the sort of internal workings that are routinely published as Directives (see http://osha.gov/pls/oshaweb/owasrch.search_form?p_doc_type=DIRECTIVES&p_toc_level=2&p_keyvalue=DATE_2008&p_status=CURRENT) for 18 directives OSHA has already published during the first eight months of 2008).

- ***General Science-Policy:***

- *Question 1.* What evidentiary standard does DOL require for departing from one of its default assumptions in favor of a case-specific alternative assumption? For example, will it judge the scientific merits of the alternative against the default under a “preponderance of the evidence” standard, a “clear and convincing” standard, a “beyond all reasonable doubt” standard, or some other standard?
- *Question 2.* What definition of “default assumption” is DOL using throughout this proposal? Under the only accepted definition of this term, a default is an assumption that is justified (either by reference to tradition or, preferably, to scientific theory and evidence) *a priori* for use in all risk assessments, and does not need to be re-argued *de novo* in each assessment unless there is evidence to the contrary. Therefore, DOL’s proposed requirement to “solicit public input [in an ANPRM] on ... key

⁴ It also appears that DOL is unaware that OSHA devoted 31 Federal Register pages (approximately 36,000 words of text, and about 100 times more material than is present in the dose-response section of the preamble of the current proposal) to supporting the choice of the input parameters for the PBPK model it used to assess the occupational risk of methylene chloride—one of dozens of examples of a “best practice” that obviates the need for the current proposal. See 62 *Federal Register*, pp. 1531-1560, January 10, 1997.

⁵ I would urge interested parties to challenge the August notice on the basis that DOL improperly may have convinced stakeholders not to comment on the risk assessment provisions.

default factors and assumptions” is illogical and/or nonsensical—if you ask the public what the default should be, you no longer have a default.

- ***Hazard Identification:***

- *Question 3.* How many positive animal studies does DOL deem sufficient to declare that a substance is a “probable” carcinogen, neurotoxin, etc.?
- *Question 4.* What is DOL’s definition of a “positive” study? Surely a crucial term (see page 50912 of the proposal) that DOL is instructing its agencies to use in conducting risk assessments would be amenable to definition within the document itself...
- *Question 5.* Does DOL accept without amendment all of the Bradford Hill criteria for evaluating human epidemiologic studies? Are there any other criteria it deems important?

- ***Dose-Response Assessment:***

- *Question 6.* In the absence of any information suggesting that a physiologically-based pharmacokinetic (PBPK) model should be used to extrapolate from rodents to humans, what allometric scaling procedure (e.g., body weight, surface area, body-weight to the $\frac{3}{4}$ power?) will DOL use? EPA, FDA, and CPSC resolved this issue **in 1992** by publishing a joint Guideline endorsing BW to the $\frac{3}{4}$ power—16 years later, OSHA has no explicit default for this crucial step, and the August proposal from DOL fails to even identify this as a risk assessment issue.
- *Question 7.* How will DOL determine whether a PBPK model proposed by an outside party is superior to the allometric default? NOTE: this is one obvious example of a “best practice” OSHA has already developed that is nowhere even hinted at in the August notice (see the 1997 methylene chloride final rule)
- *Question 8.* Which dose-response function (linear, LMS, Weibull, probit, etc.) will DOL use for carcinogenic risk assessment? Or will DOL follow EPA and use the benchmark-dose-plus-uncertainty-factor approach instead?
- *Question 9.* How will DOL evaluate information suggesting that particular tumor responses in animals are irrelevant to humans and should not be considered, on the basis of purported biological or biochemical incompatibilities across species?
- *Question 10.* How (if at all) will DOL adjust bioassay results to account for the fact that animals are typically exposed only from weaning through old age, rather than from birth until natural death?

- *Question 11.* How will DOL determine whether an agent is an initiator or promoter of carcinogenesis, or a mutagen or non-mutagen? Will it treat all agents similarly regardless of likely mechanism of action?
- **Exposure Assessment:**
 - *Question 12.* What assumptions will DOL make in the general case where industrial hygiene measurements have only been made during a portion of an eight-hour workshift? Will it continue to assume that exposure drops to zero whenever the sampling is not ongoing?
 - *Question 13.* Does DOL acknowledge that “industry-by-industry evidence relating to working life exposures” (page 50915 of the August notice) does *not* mean the existing data collected about the length of time particular workers stay with the same *employer*, but would have to be estimated from nonexistent data collected on the length of time particular workers stay within the same *occupation*?⁶
 - *Question 14.* Does DOL acknowledge that workers could move from one industry to another and yet continue to be exposed to the same substance(s) that are the subjects of a pending rulemaking, in which case even data on length of time in the industry would still be completely misleading for risk assessment purposes? Does DOL acknowledge that even if the identity of the substances change, the toxicologic mechanism of action may not? (22.5 years’ exposure to one carcinogen that can derange the *p53* pathway, followed by 22.5 years’ exposure to another carcinogen that affects the same pathway, amounts to one working lifetime of risk—if the PEL for each substance doubles because of spurious data on exposure duration, risk will double as well). How will DOL evaluate the data it receives in response to the solicitation of information in proposed 29 CFR 2.9(c)(3) in light of the multiple disconnects between what is measured, what can be measured, and what would need to be measured?
 - *Note:* in light of the two questions above, I dispute 29 CFR 2.9(c)(3). That paragraph equates “best available evidence” with industry-by-industry evidence that *cannot* adequately answer the only relevant scientific question DOL is entitled to ask under the *Benzene* decision framework: what would be the risk to actual employees if OSHA PELs were based on the 45-year assumption, versus the risk that would accrue if OSHA substituted an assumption based only on information about length of time spent with a particular employer or in a particular industry, versus

⁶ I note that DOL removed all the Tables from the previous (“secret”) version of this proposal it sent to OMB, but silence on what “working life exposures” means does nothing to change the fact that the definition used in the previous version hinged on irrelevant data tables that only measured the frequency with which surveyed employees changed *employers* (not changed occupations).

the risk that real employees face as they change employers, occupations, and exposures? Legal challenge to this rulemaking will likely explore whether the internal contradiction in this paragraph (“best evidence” is not necessarily what DOL says it is, but what science says it is) renders it arbitrary and capricious.

- ***Risk Characterization:***

- *Question 15.* How will DOL deal with unmeasured correlations in input variables to Monte Carlo analyses of uncertainty?
- *Question 16.* Which of the various “best estimates” (mode, median, mean, etc.) will DOL use to summarize uncertain information about risk?
- *Question 17.* What discount rate will DOL use to evaluate future costs and future benefits?
- *Question 18.* How will DOL fix the clearly unscientific and inappropriate practice of treating the costs of regulatory compliance as surrounded by zero uncertainty—or are the exhortations to conduct quantitative uncertainty analysis confined only to the “risk” side of the ledger (and if so, how can that possibly be justified)?

I urge the Department to withdraw or re-propose a sensible version of this proposal. Answering the questions presented above would be a useful way to start the necessary thought process.

Thank you for the opportunity to comment on this important document.

Sincerely,



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