

UAW Comments on OMB's Proposed Risk Assessment Bulletin

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These comments are submitted on behalf of the International Union, United Automobile, Aerospace & Agricultural Implement Workers of America, UAW and its 1.3 million active and retired members. On January 9, 2006, OMB released its *Proposed Risk Assessment Bulletin* for public review and comment. OMB intends the *Bulletin* to provide, "clear, minimum standards for the scientific quality of federal agency risk assessments." Advocates for strong protection of public health, safety and the environment have made a number of criticisms of this document, with which the UAW strongly agrees. These include the following:

1. **The *Bulletin* imposes unfunded mandates** for analysis on agencies whose mission is to protect public health and safety. It forces agencies to divert scarce resources from their core missions, by placing bureaucratic stumbling blocks in the way of their work. One example is the requirement to analyze, not only the risks associated with the hazards that an agency proposes to regulate, but also those associated with alternative regulatory actions that the agency does not propose to undertake. Another example is the requirement that agencies "find and examine previously conducted risk assessments on the same topic, and compare these risk assessments to the agency risk assessment. A discussion of this comparison should be incorporated into the risk assessment." This entails a tremendous amount of unnecessary and, most likely, unfunded work.
2. **The *Bulletin's* scope is biased.** It covers documents that are produced by government agencies but have never previously been understood as risk assessments, while exempting private sector-produced documents that have traditionally been understood as risk assessments, such as those produced for pesticide registration or new drug approval.
3. **The *Bulletin* requires an unconventional scientific definition** that dismisses early molecular events as non-adverse.
4. **The *Bulletin* forces agencies to devote equal time all seemingly scientific submissions**, thereby preventing the exercise of legitimate expert judgment as to which submissions are most relevant and worthy of consideration.
5. **The *Bulletin* imposes a one-size-fits-all approach** across agencies with different missions and statutes with different goals.

In addition to the above, the UAW would like to offer detailed comments about the *Bulletin's* application to NIOSH Current Intelligence Bulletins. It is the UAW's position that the burdens that would be imposed on the production of these documents are similar to the burdens that would be imposed on other actions that protect public health and safety. Hence none of the flaws identified in the application of the *Bulletin* to these

NIOSH activities could be resolved simply by exempting them from the reach of the OMB *Proposed Risk Assessment Bulletin*. For illustrative purposes, these comments discuss a Current Intelligence Bulletin related to an occupational hazard that affects our membership. The production of this Current Intelligence Bulletin would have been unduly burdened had the OMB *Proposed Risk Assessment Bulletin* been in effect at the time.

Toluene diisocyanate (TDI) is widely used in the manufacture of flexible polyurethane foams, elastomers, surface coatings, fibers, sealants, and adhesives. Many of these products are used in the manufacture of automobiles and automobile parts. As a result, many of our members are exposed to TDI. *NIOSH Current Intelligence Bulletin 53: toluene diisocyanate (TDI) and toluenediamine (TDA); evidence of carcinogenicity* was published in 1989 because chronic toxicity data from animal studies provided evidence of an association between cancer and exposure to commercial-grade TDI (an 80:20 mixture of 2,4- and 2,6-TDI). The tumorigenic responses observed in both rats and mice met the criteria of the Occupational Safety and Health Administration (OSHA) Cancer Policy for classifying a substance as a potential occupational carcinogen. NIOSH recommended that in the face of this evidence, it was prudent to control exposure to all TDI and TDA isomers as if they were carcinogens, which meant limiting exposures to the lowest feasible concentrations.

It is important to note that NIOSH did not assert that there was scientific proof that all TDI and TDA isomers were carcinogenic. NIOSH however, was sufficiently concerned that they might be carcinogenic that the agency believed that warning employers and practitioners of occupational health and safety was the wise course of action. The effect, if not the intent, of the *Proposed Risk Assessment Bulletin* would be to silence all such wisdom, prudence and common sense on the part of civil servants dedicated to protecting the public's health and safety. Even where total silence would be avoided, there would still be a delay in getting urgent information to those who need it in order to protect public health and safety.

NIOSH Current Intelligence Bulletin 53 presents major routes of occupational exposure to commercial grade TDI, chemical and physical properties, and *in vitro* mutagenicity. It has a lengthy discussion of the animal studies that prompted the publication and of independent reviews of these studies. Finally, it presents the known human health effects. If *Current Intelligence Bulletin 53* were subject to the requirements of OMB's *Proposed Risk Assessment Bulletin*, either it would not be published or it would take considerably longer for its recommendations to reach those responsible for protecting workers. This is because, under OMB's *Bulletin*, NIOSH would have to add the following:

- a definition of the relevant exposure scenarios,
- the type of dose-response relationship,
- a specification of each population addressed,
- the expected risk or central estimate of risk for the specific populations,
- each appropriate upper-bound or lower-bound estimate of risk,
- each significant uncertainty identified in the process of the assessment of risk and the studies that would assist in resolving the uncertainty,

- a discussion regarding the nature, difficulty, feasibility, cost and time associated with undertaking research to resolve key scientific limitations and uncertainties,
- peer-reviewed studies that support, are directly relevant to, or fail to support the estimates of risk,
- the methodology used to reconcile inconsistencies in the scientific data, and
- placement of the risk in context with other risks familiar to the target audience.

NIOSH would also have been required to make a draft of this document available for notice and comment and to respond to all significant comments, including all comments that claim to be based on science. When we remember that the original purpose of this document was to provide information in a timely manner to people who are responsible for protecting the health and safety of workers, it seems unreasonable and counterproductive that all these requirements should be placed on this or any Current Intelligence Bulletin. It seems even more unreasonable and counterproductive when we remember that the Current Intelligence Bulletin does not require employers to do anything nor does NIOSH have the legal authority to promulgate enforceable regulations.

One can only conclude that either OMB is woefully unaware of the practical consequences of its own *Proposed Risk Assessment Bulletin* or that it intends to impede government agencies from providing information relevant to the public's health and safety in a timely manner that will permit its prudent use. Either way, the proposal that OMB has produced is unconscionably broad and prescriptive. It will prevent those government agencies responsible for protecting health, safety and the environment from carrying out their missions. This may even be the intent of the proposal. It should be withdrawn.