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To whom it may concern,

Yesterday I submitted Environmental Working Group's comments on OMB's proposed Risk Assessment Bulletin. Unfortunately, this morning I discovered that I had submitted a non-final version of these comments in error. Attached are EWG's final comments. Please replace the previous version that I sent with this version. I have also re-submitted these revised comments via e-mail. I apologize for any inconvenience.

Best,

Renee Sharp

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Comments on OMB's Proposed Risk Assessment Bulletin

Environmental Working Group
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The Environmental Working Group (EWG) is a Washington, D.C.-based research and advocacy organization that has been examining federal risk assessments for more than 13 years. We are deeply concerned about the Office of Management and Budget's (OMB) proposed Risk Assessment Bulletin. In our opinion this proposed guidance is at best problematic and at worst dangerous, depending on how it is interpreted and implemented.

Before addressing the Bulletin's flaws, EWG would like to acknowledge that the guidance contains a few positive elements. We welcome, for instance, its emphasis on making risk assessments more transparent: It is important for the public to be able to understand how the federal government deals with potential environmental and public health threats. EWG also appreciates that the guidance mentions children as a potentially susceptible population, for this is too often over-looked in risk assessments.

Overall, however, the negatives of OMB's proposed guidance *far* outweigh the positives:

First, we might support making risk assessments more comprehensive – as this guidance proposes we do – if this did not too often require significant additional time, effort, and resources. But in the real world, the many layers of additional analyses mandated in the OMB proposal will only further delay an already lengthy risk assessment process, and will therefore significantly impede the ability of federal agencies to actually take action to protect public health. Consider arsenic, as one example. Congress directed the Environmental Protection Agency (EPA) to update the grossly inadequate federal drinking water standard for arsenic in 1974, 1986, and again in 1996. Yet it took the EPA more than a quarter century to complete its revised risk assessment: Even then, the agency didn't adopt its new, more health-protective standard until 2001 – and this still didn't actually go into effect until January of this year. It is frightening to imagine how long it might have taken the EPA to set a new drinking water standard if the agency had to meet all of the requirements outlined in the OMB's risk assessment guidance.

Second, EWG would also support making risk assessments more comprehensive if this meant that federal agencies were required to consider factors such as aggregate exposures, interactions between chemicals, and vulnerable populations more fully. In contrast, the guidance lays out a set of requirements that could collectively be termed "the full employment act for industry toxicologists." In particular, we are concerned with OMB's requirement that risk assessors evaluate and discuss alternative theories, data, assumptions, and studies; the requirement that agencies "have procedures in place" to assess new information that might alter a previously conducted influential risk assessment; the suggestion that risk assessors calculate a weighted average of results from alternative models; and the general requirement for reproducibility. Together, these requirements would provide little or no public health benefit, while dramatically increasing costs. These requirements would also provide considerable advantage to parties with lots of time, money, and toxicologists – typically industries responsible for the pollution under review – to influence, challenge, and delay influential risk assessments under the guise of "improving" them.

Third, we take issue with the Bulletin's emphasis on providing "central" or "expected" risk estimates. This emphasis is at odds with the current and appropriate regulatory interest in protecting sensitive or highly exposed subpopulations, not to mention the growing literature showing how the timing of exposures encountered by the fetus and infant can significantly increase the risk of adverse outcomes. Adequately protecting public health means that risk assessors must look beyond the "average adult male," which has been the standard assumption for most federal agencies for many years, and look at the most at risk among us. Such sentiments have been mirrored by the EPA's Children's Health Protection Advisory Committee, the EPA's Guidelines for Carcinogen Risk Assessment, and the National Academy of Sciences, among others. (CHPAC 2006, EPA 2005, NAS 1993.) If risk assessors follow OMB's guidelines they will be taking a profound step backward –in terms of both science and public health.

Third, the guidance instructs risk assessors to distinguish between "adverse" and "non-adverse" effects, and defines adversity as "a function impairment or pathological lesion that affects the performance of the whole organism or reduces its ability to withstand or respond to additional environmental challenges." This definition of "non-adverse" effects could be interpreted to include reduced sperm count or motility, increased cholesterol, reduced thyroid hormone levels, small decreases in IQ, mild motor effects, skin discoloration and other changes that could be highly problematic to an individual –not to mention at the population level –but would not be considered under this guidance. (Potashnik and Porath 1995, Salkever 1995, WHO 1999, ATSDR 1999, EPA 1999, Trasande 2005.) Population-wide effects that are difficult to discern in individuals would be extremely difficult to regulate under these criteria. It is no exaggeration to say that were these criteria in effect, it is quite possible that lead would still be in gasoline, DDT would be in widespread use, and PCBs would be the electrical insulator of choice.

The public health and economic costs of failing to control these toxic compounds at the population level are enormous. Recent research on the lifetime costs associated with even small decreases in IQ underscores this point. Salkever (1995), for example, estimated that a single IQ point decrement is associated with a lifetime earning loss of 3.2 percent for girls, and 1.9 percent for boys. Using these statistics, along with the associations between blood mercury and IQ, Trasande et al. (2005) calculated that anthropogenic mercury pollution is associated with $8.7 billion worth of lost earnings for each year's birth cohort. Similarly, Grosse et al. (2002) used the link between IQ and blood lead to calculate the economic benefit of banning lead from paint and gasoline. They estimated that the nation-wide savings for each year's birth cohort is in the range of $110 to $319 billion. Such research shows that even small changes in IQ caused by environmental contamination can have drastic effects when considered population-wide. And it should be noted that mercury and lead are not the only compounds known to have effects on brain function at relatively low levels. If we really want to protect public health, therefore, we need to be looking at how to prevent precursor effects, not clearly not just those considered "adverse" as defined by this guidance.

Futhermore, we are concerned with the exemptions granted by the guidance, which seem to include all pesticides and most FDA-regulated products. It is puzzling to us why the OMB would exclude such large classes of risk-assessments from this guidance if the goal is truly to "improve the quality, objectivity, utility, and integrity of the information disseminated by the federal government to the public." Why should pesticides be treated differently than mercury or trans-fatty acids when it comes to characterizing risk?

Perhaps one reason for exempting pesticides is that the OMB guidance, if followed, would run headlong into legally mandated risk assessment requirements in the federal Food Drug and Cosmetic Act (FFDCA).

The Food Quality Protection Act (FQPA) of 1996 amended FFDCA to require specific protections from pesticides for infants and children. These amendments set out explicit factors that must be considered in the assessment of pesticide risk to infants and children, and are generally considered the toughest, most thorough and health protective risk assessment criteria in all of U.S. law. As such, FQPA provides an example of how making risk assessments more comprehensive can lead to increased public health protection. This is in direct contrast to most of the requirements laid out in the OMB Bulletin, which will make risk assessments more comprehensive, but it ways that will almost certainly lead to *less* public health protection.

FQPA requires the EPA Administrator, for example, to assess the overall the risk of pesticides to children in ways that are designed to identify disproportionate exposures or unique vulnerabilities among children, so that protective measures can be taken. The law requires that risk assessments be conducted based on: (1) consumption patterns likely to result in disproportionately high consumption of foods containing or bearing pesticide chemical residues in comparison to the general population; (2) special susceptibility to pesticide chemical residues, including neurological differences between infants and children and adults and effects of in utero exposure to those residues; and (3) the cumulative effects on this group of such residues and other substances having a common mechanism of toxicity. Moreover, FQPA requires that the Administrator "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue," and publish a "specific determination" regarding the safety of the residue for infants and children. And on top of all this, FQPA also requires that the Administrator and consider information on "aggregate exposure levels of consumers" and the "potential effect on humans of a pesticide chemical residue similar to that produced by endocrine effects" when establishing, modifying, leaving in effect, or revoking a pesticide tolerance. [7 U.S.C. § 346a, subsections (b)(2)(C) (b)(2)(D)]

Following the OMB guidelines would clearly violate FQPA's tough, mandatory standards, which could explain why pesticides are exempted from the OMB guidelines. Simply put, OMB risk assessment methods would be illegal for pesticides regulated under the Food Drug and Cosmetic Act: The guidelines would represent a clear weakening of the health protection in the law and are contrary to statutorily mandated risk assessment criteria in the FFDCA.

This raises fundamental questions of why the government should institutionalize a double standard for risk assessments, where pesticides are regulated in a thorough and very health protective way, and all other potentially hazardous materials are subjected to OMB's weaker, byzantine, less health protective approaches. Major chemical and pesticide manufacturers have managed to comply with these pesticide risk assessment and safety standards for a decade, with no discernable adverse economic impacts, and with substantial benefits to the public health. A more logical approach to improving risk assessments across all federal agencies would be to make them all consistent with the methods mandated by FQPA, and currently used by the pesticide office of the EPA.

And as we alluded to earlier, there are several serious errors of omission in the guidance. For example, while the document places extensive focus on characterizing the uncertainties inherent within the studies, models, and assumptions that are used in risk-assessment, the guidance makes almost no note of a much larger source of uncertainty. That is, all of the data that we don't have, the endpoints not studied, the age-groups not considered, the potential additive or synergistic effects with other chemicals that not evaluated. This is a major oversight.

Finally, EWG would like to note that part of the danger of this document lies in its subtlety. That is, many of the negative consequences we describe here stem from vaguely worded requirements that on the surface may appear reasonable in theory or when viewed in isolation. Yet together, these

requirements will cripple the federal government's ability to take action to protect public health. There is great potential for this guidance to slow down the risk assessment process to virtual stand still by imposing excessive analytical requirements, and providing many opportunities for those with a financial stake in a risk assessment outcome to influence, challenge, or delay the process.

Thank you for considering our views.

Sincerely,

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