Proposed Risk and Technology Assessment Review
Written Statement for Science Advisory Board Teleconference
December 19, 2006

The Environmental Protection Agency (EPA) Office of Air and Radiation has requested that the Science Advisory Board (SAB) review its proposed Risk and Technology Review (RTR) assessment plan, which it intends to use to set standards for sources of hazardous air pollutant (HAP) emissions under § 112(f)(2) of the Clean Air Act (the "Act"). Technology-based standards for these sources have already been established under § 112(d) of the Act, and EPA must now characterize the remaining or residual risk and adopt more stringent standards if necessary to protect public health with an ample margin of safety.

EPA expects that, by mid-April 2007, it will have completed eight residual risk standards (RTR I). The RTR assessment plan describes a streamlined approach that EPA intends to use for the remaining residual risk standards (RTR II). EPA will use the 2002 National Emissions Inventory as a starting point for RTR II assessments. Emissions and facility data for the sources to be addressed will be used to derive annual emission rates from these sources. After Agency and public review, EPA will use apply its preferred dispersion modeling system to them to estimate ambient concentrations. For potential carcinogens, EPA will then estimate individual and population risks of lifetime exposure by applying cancer potency factors to these ambient concentrations.

Others have commented on errors in the emissions data upon which EPA plans to rely, and the proposed opportunity for public review may address some of these concerns. The proposed approach to dose-response assessment and risk characterization, however, suffers from more fundamental problems: it is inconsistent with the Benzene NESHAP decision framework that EPA must follow in developing residual risk standards,[1] with EPA's Guidance for Risk Characterization,[2] and with EPA's Guidelines for Carcinogen Risk Assessment.[3]

The Benzene NESHAP decision framework and these guidelines address how carcinogen risk assessment is to be conducted and how the product of the risk assessment is to be used in making regulatory decisions and other aspects of risk management. None of these documents

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[1] 58 *Fed. Reg.* 38044 (September 14, 1989).

[2] EPA Science Policy Council (February 1995).

[3] 70 *Fed. Reg.* 17766 (April 7, 2005).

contemplates that EPA will, without more, multiply estimated ambient concentrations by cancer potency factors to derive emission limits.

Under the general framework outlined in the 1989 Benzene NESHAP, and codified in § 112(f)(2), EPA is to conduct a two-step process in providing "an ample margin of safety to protect public health" following a determination that standards promulgated pursuant to subsection § 112(d) "do not reduce lifetime excess cancer risks to the individual most exposed to emissions from a source in the category or subcategory to less than one in one million [10^{-6}]." As outlined in the Benzene NESHAP, the 10^{-6} individual additional cancer risk level is not a "bright line" mandated level of protection for establishing residual risk standards, but rather a trigger point to evaluate whether additional reductions are necessary to provide an ample margin of safety to protect public health. There is no single risk level establishing what constitutes an ample margin of safety. *Id.* Rather, the Benzene NESHAP approach, subsequently codified in §112(f)(2), is deliberately flexible, requiring consideration of a range of factors (among them estimates of quantitative risk, incidence, and numbers of exposed persons within various risk ranges; scientific uncertainties; and weight of evidence) when determining acceptability of risk. 54 *Fed. Reg.* at 38045. The determination of what represents an "acceptable" risk – the first step in the Agency's ample margin of safety determination – is based on a judgment of "what risks are acceptable in the world in which we live." 54 *Fed. Reg.* at 38045. Determination of ample margin of safety, the second step of the process, requires further consideration of these factors, plus consideration of technical feasibility, cost, economic impact, and other factors. 54 *Fed. Reg.* at 38046. In both steps of the process, EPA is required to take into account the weight of the scientific evidence on which a cancer potency factor is based, and to address scientific uncertainty.

EPA's Guidance for Risk Characterization is very clear on this point:

> Often risk assessors and managers simplify discussion of risk issues by speaking only of the numerical components of an assessment. That is, they refer to the alpha-numeric weight-of-the-evidence classification, unit risk, the riskspecific dose or q_1* for cancer risk . . . to the exclusion of other information bearing on the risk case. However, since every assessment carries uncertainties, a simplified numerical presentation of risk is always incomplete and often misleading. For this reason, the NRC and EPA risk assessment guidelines call for "characterizing" risk to include quantitative information, a related numerical risk estimate and a discussion of uncertainties, limitations, and assumptions – default and otherwise.

Similarly, the Guidelines on Carcinogen Risk Assessment state:

> Risk characterization is a necessary part of generating any Agency report on risk, whether the report is preliminary – to support allocation of resources toward further study – or comprehensive – to support regulatory decisions. In the former case, the detail and sophistication of the characterization are appropriately small in scale; in the latter case, appropriately extensive. Even if a document covers only parts of a risk assessment (hazard and dose-response analyses, for instance), the results of these are characterized.

70 *Fed. Reg.* at 17808.

The RTR assessment plan does not address how scientific uncertainty and weight of the evidence considerations will be dealt with in the risk assessments that underlie specific residual risk standards. Section 4, Risk Characterization, states that "[e]stimates of health risk should be presented in the context of uncertainties and limitations in the data and methodology," but the examples given in Sections 4.1 and 4.6 suggest a focus on generic issues, such as individual v. population risk, sensitive subgroups, background concentrations, mixtures, etc. The uncertainties that underlie derivation of potency factors are largely dismissed on the basis that they are not quantifiable. This is a surprising statement, given the emphasis currently being placed by the EPA Science Adviser and the National Academy of Sciences on identifying and characterizing the uncertainties in risk assessment. Nowhere is there any indication of how the scientific uncertainties incorporated into a single potency factor will be disaggregated and taken into account, even though the Guidelines quoted above indicate that the risk characterization for an assessment that supports a regulatory decision must be "comprehensive."

A recent residual risk standard proposed by EPA would establish emission caps for halogenated solvent cleaning based on the streamlined methodology described in RTR II.[4] The "risk assessment" upon which EPA relied simply provided estimated lifetime exposure concentrations multiplied by cancer potency factors to derive a range of emission limits.[5] Nowhere in the record of that rulemaking is there any indication that EPA considered scientific uncertainty or even attempted to characterize the risk. Nowhere did EPA address the scientific weight of the evidence supporting the application of such potency factors for methylene chloride, trichloroethylene, or perchloroethylene, none of which is a known human carcinogen. Yet the

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[4] 71 *Fed. Reg.* 47670 (August 17, 2006).

[5] Risk Assessment for the Halogenated Solvent Cleaning Source Category.

Benzene NESHAP decision framework is very explicit that a residual risk determination must have a scientific basis beyond simply a potency factor:

> A principle that accompanies these numerical goals [*e.g.*, 1 in a million, 1 in a thousand risk] is that while the Agency can establish them as fixed numbers, the state of the art of risk assessment does not enable numerical risk estimates to be made with comparable confidence. Therefore, judgment must be used in deciding how numerical risk estimates are considered with respect to these goals. As discussed below, uncertainties arising from such factors as the lack of knowledge about the biology of cancer causation and gaps in data must be weighed along with other public health considerations. Many of the factors are not the same for different pollutants.

54 *Fed. Reg*. at 38045. Even more explicitly, in discussing how EPA must assess risk from compounds that are not known human carcinogens, the Benzene NESHAP notes:

> Particular attention will also be accorded to the weight of evidence presented in the risk assessment of potential human carcinogenicity or other health effects of a pollutant. While the same numerical risk may be estimated for an exposure to a pollutant judged to be a known human carcinogen, and to a pollutant considered a possible human carcinogen based on limited animal test data, the same weight cannot be accorded to both estimates. In considering the potential public health effects of the two pollutants, the Agency's judgment on acceptability, including the MIR [maximum individual risk], will be influenced by the greater weight of evidence for the known human carcinogen."

54 *Fed. Reg.* at 38046.

The Science Advisory Board should look carefully at the RTR assessment plan to ensure that it is consistent with the Benzene NESHAP decision framework and EPA guidance on risk assessment and risk characterization. EPA should not, in the interest of a "streamlined" approach, eliminate the elements of risk assessment that provide it a measure of scientific integrity -- those involving scientific judgment and common sense.