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Mr. Chairman and Members of the Committee, I welcome the opportunity today to testify on EPA's plans for implementing the residual risk program, which is one component of a broader strategy mandated in the Clean Air Act Amendments of 1990 to protect public health and the environment against toxic air pollution.

The 1990 Amendments called for a two-phased approach to reducing toxic air emissions from major industrial sources. First, EPA is to issue industry-by-industry standards to ensure that all sources are appropriately controlled. Second, in the residual risk phase, EPA is to assess the remaining risks from those industries and, if necessary, require reductions in toxic air emissions to protect health and the environment.

Congress reached a bipartisan compromise on the residual risk provisions in 1990 after years of dialogue and debate over the best way to achieve effective and reasonable air toxics control. A decade later, EPA continues to believe that it makes sense to evaluate whether Maximum Achievable Control Technology (MACT) standards provide the public with adequate health and environmental protection, and to take action if they do not. Although the job will not be easy, EPA with the aid of the scientific community (including the National Academy of Sciences) has developed risk assessment methodologies

and risk management procedures that allow for making reasoned decisions on whether to require further emissions reductions, based on the available scientific information and consideration of uncertainties.

Today, I will describe the general approach to risk assessment and risk management that EPA will use in deciding whether further reductions in toxic air emissions are needed from industrial facilities that have met technology-based emission limits. To set the stage, it is useful to put the program in context by providing some historical background and outlining EPA's overall air toxics strategy.

Air Toxics and the 1990 Clean Air Act Amendments

At the time Congress amended the Clean Air Act (CAA) provisions on hazardous air pollution in 1990, it was well established that the public is exposed to air toxics such as lead, benzene, dioxin, mercury, chromium, and other compounds. It was also known that toxics found in the air can cause cancer or other serious health effects such as neurological damage, miscarriages, birth defects, or lung damage.

Industry reports required by the Emergency Planning and Community Right-to-Know Act of 1986 revealed that manufacturing industries alone had emitted more than 2.7 billion pounds of toxic chemicals into the air in 1987. Risk assessments indicated that individuals living near some industrial facilities faced potentially high cancer risks. Studies found that millions of people in American cities faced some elevated risks from a complex mixture of toxic chemicals emitted by multiple sources ranging in size from big petrochemical plants to dry cleaners to motor vehicles. And atmospheric deposition of hazardous air pollutants was identified as contributing to toxic pollution in the Great Lakes. Neighboring states and Canada had issued health advisories against eating certain varieties of fish caught in the Great Lakes because they contained elevated levels of PCBs, mercury and other toxics.

All this was highlighted in congressional hearings. During the 1990 revision of the Act, Congress concluded that the pre-1990 hazardous air pollutant provisions had provided fertile ground for 20 years of emotional and often endless debate and litigation. Those provisions called for EPA to list and regulate

hazardous pollutants one at a time based on the risks they posed. The result was gridlock. In 20 years, EPA listed only eight pollutants and regulated only seven. The regulations covered only some of the sources emitting those pollutants.

In response, Congress overhauled the Clean Air Act to ensure effective actions to protect public health from nearly 190 toxic air pollutants. The Act mandates a two-phased approach: cut toxic emissions substantially by requiring maximum achievable controls considering costs on major sources, and use targeted approaches to reduce particular types of risks.

In the first phase, EPA is directed to issue technology-based emissions standards on an industry-by-industry basis to bring down the amount of toxics in the air and reduce exposure to air toxics among citizens living nearby. This approach -- requiring dirtier facilities to achieve the level of performance already being achieved by cleaner facilities of the same type -- has proven very successful. MACT standards issued to date will reduce annual emissions of air toxics by 1.5 million tons -- many times the reductions achieved by standards issued during the 1970-90 period. To provide industry with greater flexibility on ways to comply with MACT standards, we develop numerical emissions performance standards whenever feasible, and typically include other features such as alternative compliance options or emissions averaging.

As we work to complete the MACT standards, we are implementing the second phase of the toxics program targeted to particular types of risks. Key components of this second phase include:

- assessing residual risks of toxic air emissions from MACT-regulated sources to determine whether further controls are needed to protect public health and the environment.
- implementing the Integrated Urban Air Toxics Strategy, which is aimed at reducing risks in urban areas from 33 priority pollutants emitted by small “area” sources, motor vehicles and other sources.

- continuing assessments of atmospheric deposition of air toxics into the Great Lakes, and considering additional actions that may be needed to reduce emissions of those toxics.
- conducting National Air Toxics Assessment activities to provide citizens, localities, states and ourselves with better information on toxic emissions, exposure and risk.

The Residual Risk Program

In crafting the 1990 Amendments, Congress recognized that in the case of some industries, emissions reductions achieved by the MACT program might not be sufficient to protect public health and the environment. So the 1990 Amendments direct EPA to evaluate the remaining risks from each regulated source category. If necessary to protect public health or the environment, EPA is to issue residual risk standards requiring further emissions reductions. Any such standards are to be issued within eight years of the date the MACT standard was issued (nine years for certain early standards).

The details of these provisions represent a hard-won compromise achieved by the 102nd Congress, which spent as much time developing the residual risk provisions as it did on any portion of the 1990 Amendments. The provisions reflect attention to a variety of conflicting concerns -- the concerns of people exposed regularly to air toxics in the air that they breathe, the economic concerns of industrial facilities, and concerns about the uncertainty, imprecision and complexity associated with risk assessments of toxic air pollutants.

Those concerned about elevated risks from air toxics include minority and low-income residents who often are disproportionately represented in neighborhoods near industrial sites. In evaluating residual risks, EPA will look closely at potential exposures in nearby neighborhoods and be cognizant of subpopulations such as children and pregnant women who may be especially vulnerable to some toxic pollutants.

For many source categories, this program will be challenging to implement because of data gaps and uncertainties involved with risk assessments for hazardous air pollutants, and differing views among stakeholders over how risk assessors and risk managers should account for uncertainties. These issues are not new. Under the old pollutant-by-pollutant regulatory system in the 1970 Clean Air Act, these issues severely hindered implementation of the federal air toxics program. While there have been great strides made in the field of risk assessment since the 1990 Amendments, risk assessment by definition will always entail uncertainties.

Knowing this, Congress designed the residual risk provisions of the1990 Amendments to provide for decision making in the face of uncertainties. To lay the groundwork for the residual risk program, Congress required three reports -- two by independent panels of scientists, and one by EPA -- to address issues concerning risk assessments and risk management. Congress also provided a detailed framework to guide EPA's residual risk decisions in a world in which we don't have all the information we would like.

Today, all three statutorily required reports on risk assessment and risk management are complete. A 1994 report by the National Research Council (NRC) of the National Academy of Sciences, mandated by section 112(o) of the CAA , reviewed EPA's risk assessment methods. A 1997 report by the congressionally mandated Commission on Risk Assessment and Risk Management (CRARM), mandated by section 303 of the 1990 Amendments, examined risk assessment and risk management issues relevant to hazardous substances under various federal laws. After evaluating these reports, EPA in 1999 provided a major Report to Congress describing how the Agency will implement the residual risk program, using the available scientific information and methods.

EPA's implementation approach for the program reflects the suggestions of the scientific committees. For example, the NRC report noted that neither the resources nor the scientific data exist to

perform a full-scale risk assessment on all the chemicals listed as hazardous air pollutants (HAPs) and their sources. Therefore, the NRC supported an iterative approach to risk assessment of source categories emitting HAPs. This approach would start with relatively inexpensive screening techniques used to determine whether the evaluated source category is below the statutory level of concern, or whether we need to conduct a more refined analysis before we can make a determination. (We will not regulate based on the results of a screen.) As a particular situation warranted, we would move to a more resource-intensive level of data-gathering, model construction and model application to produce a risk assessment providing greater certainty. The result would be a process that supports the risk management decisions required by the CAA and provides incentives for better data and further research, without the need for costly case-by-case evaluations of individual chemicals of every facility in every source category. The CRARM agreed that the EPA should use an iterative approach when conducting risk assessments and elaborated on the general approach presented by the NRC. The Agency is using an approach that is consistent with that presented by the CRARM to undertake its residual risk assessments.

After a residual risk assessment is conducted, EPA must determine whether a residual risk standard should be established to achieve further emissions reductions. Specifically, EPA is to issue a residual risk standard for a source category if required "to provide an ample margin of safety to protect the public health, or to prevent, taking into consideration costs, energy, safety and other relevant factors, an adverse environmental effect." Congress provided specific guidance on how this residual risk decision is to be made for hazardous air pollutants that lack a health effects threshold (e.g., many carcinogens) by endorsing the framework EPA developed for the 1989 benzene national emissions standard. This framework -- developed through notice and comment rulemaking in response to a 1987 decision by the Court of Appeals for the District of Columbia Circuit -- calls for a two-step decision-making process considering multiple factors.

In the first step, EPA determines a "safe" or "acceptable" risk level that considers all health information -- including the risk level of highly exposed individuals, the number of people exposed within each lifetime risk range, the overall incidence of health effects, the science policy assumptions associated with the risk measures, and the weight of evidence that a pollutant is harmful to health. EPA ordinarily will presume that a 1 in 10,000 lifetime risk of cancer to the individuals exposed to the maximum level of a pollutant represents the upper end of the range of acceptable risk. However, this is not a rigid line; rather it is a presumption to be weighed with the other factors.

In the second step, EPA determines the level of the enforceable emissions standard needed to provide an "ample margin of safety." In choosing this level, EPA considers again all health information -- including the number of persons at risk levels higher than approximately 1 in 1 million, the nature of the assumptions underlying the risk assessment, and weight of evidence that a pollutant is harmful. In determining the margin of safety, EPA also considers costs and economic impacts of controls, technological feasibility and other relevant factors.

This congressionally endorsed approach is consistent with risk management approaches of other EPA programs intended to broadly protect public health. For example, other EPA programs

use a risk management range of 10^{-6} to 10^{-4} under their reasonable maximum exposure scenario to guide their decision-making for carcinogens.

Also, the methods used to generate risk estimates for the residual risk program are consistent with those of other EPA programs. To address uncertainties, EPA makes scientifically sound judgments and assumptions about hazard and exposure to generate "reasonably conservative" risk estimates. By "conservative" we mean that true risks may be higher, but are likely to be lower. There are parameters that can substantially increase or decrease the estimated risk; EPA does not use conservative

assumptions for all of these. For example, where we lack adequate information to support a quantitative assessment for a pollutant, we implicitly assume that the risks from that pollutant are zero. The result, in the end, is that our risk estimates are plausible and do not represent worst case estimates.

This Committee has expressed interest in the findings of an EPA Science Advisory Board (SAB) panel that recently reviewed a case study illustrating the approach EPA plans to use to conduct risk assessments for the residual risk program. The SAB subcommittee said that EPA methodology "is consistent with the methodology described in the Report to Congress," (which the Science Advisory Board reviewed and supported in 1998), and that "the assumptions used are consistent with current methods and practice." The subcommittee also made valuable substantive comments and suggestions for improvements, which EPA is incorporating. While the SAB did not find any "showstoppers" (their word) with the approach used, they did identify several issues that should be addressed such as a more fully evaluated model to predict exposure to toxics through multiple media, and improved data collection efforts. The SAB expressed particular concern about the availability of sufficiently precise scientific information that would support residual risk analysis. EPA is incorporating the Science Advisory Board's suggestions into our residual risk assessments. We are providing the Committee with a copy of our formal response to the SAB. As we stated to the SAB, EPA will obtain peer review on the full case study risk assessment when it is completed.

As mentioned earlier, we are working to improve our data on air toxics (through our NATA or National Air Toxics Assessment activities) and our risk assessment methods. For example, we are improving the National Toxics Inventory, which is a repository of source specific air toxics emissions data from states; working with states and cities to expand monitoring of ambient air toxics levels (a plan which received a positive review from the SAB); and developing a new, better, multi-pathway methodology in TRIM (Total Risk Integrated Methodology), which has received two very favorable reviews from the

SAB. We are also conducting national- and local-scale air quality, multimedia and exposure modeling to help characterize risks associated with air toxics exposures. Furthermore, we have been working with our colleagues in the Office of Research and Development for nearly two years to develop the Agency's Air Toxics Research Strategy. This strategy helps us to prioritize our research efforts on health and environmental effects and exposures to ambient and indoor sources of air toxics. Over time, these activities will help us set program priorities, provide the public with risk information, and track progress toward meeting national air toxics program goals.

In light of current uncertainties, some may suggest that EPA wait for more complete information before attempting to assess and address any risks from air toxics remaining after MACT. The flaw in this approach is that, in some cases, individuals may continue to be exposed to unsafe levels of toxics around these facilities while we fail to act based on information that is available now. For other source categories, available information may reassure concerned citizens that the facilities near them are well controlled. In the field of environmental protection, as in much of life, there are few decisions for which we would not like to have more information. The

reality is that to avoid paralysis, we must make reasoned choices based on the information we have.

Looking ahead, EPA has no preconceived notions of what residual risk analyses will show. Our plan is to use the available information to assess residual risks from each source category. We will use the most up-to-date credible and relevant information on chemical hazards. Taking into account uncertainties and the assumptions in the risk analysis, we will make a reasoned judgment as to whether the weight of the evidence supports requiring further emissions reductions to protect public health and the environment. If there is not sufficient evidence of a threat, EPA will not issue a residual risk standard. If toxic emissions are unsafe based on the framework provided by Congress, EPA will take protective

action.

Mr. Chairman, thank you for the opportunity to testify. I would be pleased to answer any questions that you may have.