Analysis&Perspective

CLEAN AIR ACT

RESIDUAL RISK STANDARDS

The 1990 amendments to the Clean Air Act required EPA to establish emission standards to control any ''residual risk'' that remained following implementation of the rules requiring the installation of maximum achievable control technology to control hazardous air pollutants. In this article, the authors describe the statutory requirements for residual risk and the methodology EPA proposed for establishing residual risk standards. They also describe the residual risk standards for coke ovens and identify issues regarding EPA's methodology for these and future standards.

Residual Risk Standards: 'Phase Two' of Clean Air Act's Air Toxics Provisions

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In 1990, Congress amended the Clean Air Act and imposed a two-phase program for regulating hazardous air pollutants (HAPs). In the first phase, Congress directed the Environmental Protection Agency to establish technology-based emission standards requiring the installation of maximum achievable control technology (MACT) on HAP-emitting equipment. In the second phase, Congress directed EPA to establish emission standards to control any ''residual risk'' that remained following implementation of the MACT standards. EPA issued 91 MACT standards from 1991 to 2004. On Aug. 9, 2004, EPA proposed its first residual risk standard, for coke oven batteries, which became final March 31, 2005.

In this article, we first summarize how EPA regulated hazardous air pollutants before and after the 1990 Clean Air Act Amendments. We then provide a detailed description of the statutory requirements for residual risk, and the methodology EPA proposed for establishing residual risk standards in its report to Congress. Finally, we describe the residual risk standards for coke ovens and identify issues regarding EPA's methodology for these and future standards.

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The opinions expressed here do not represent those of BNA, which welcomes other points of view.

Hazardous Air Pollutant Standards Before 1990

Prior to 1990, the Clean Air Act required EPA to identify and list HAPs that were ''reasonably'' expected to cause a serious health risk. Once it listed a HAP, EPA was then required to set an emission standard for that HAP within 180 days. These emission standards were, and are, known as the National Emission Standards for Hazardous Air Pollutants, or NESHAPs. Congress required the NESHAPs to be set ''at the level which in [EPA's] judgment provides an ample margin of safety to protect the public health.'' This was a difficult mandate for EPA, as environmental groups seized upon the statutory language and argued that, particularly for carcinogens, zero was the appropriate standard for most, if not all, compounds. Industry, on the other hand, argued that interpreting and applying the statute in such a manner would be crippling to industry. EPA attempted to find a middle ground and began issuing NESHAPs based on best available pollution control technology, as long as the standards were below the level at which harm to humans had been demonstrated. EPA's attempted compromise appeared to satisfy few stakeholders and led to much argument and litigation.

In *Natural Resources Defense Council v. U.S. Environmental Protection Agency*, (referred to here as the *Vinyl Chloride* case), the U.S. Court of Appeals for the District of Columbia Circuit adjudicated a challenge to

EPA's vinyl chloride NESHAP.[1] In that case, the Natural Resources Defense Council (NRDC) argued that EPA was required to establish the standard for vinyl chloride based exclusively on health-related factors.[2] And, NRDC argued, in the face of uncertainty regarding possible adverse public health effects for that pollutant, EPA had to prohibit all emissions. The Vinyl Institute, which intervened on behalf of industry, advocated a very different, two-step approach: first, establishing an ''acceptable'' exposure level; and second, identifying an ''ample margin of safety,'' considering economic and technological considerations. EPA, in turn, objected to both of these approaches and countered that Congress had authorized it to set HAP emission standards that required emissions reduction to the lowest level attainable by best available control technology as long as such a level was below that at which harm to humans had been demonstrated.[3]

The D.C. Circuit found neither NRDC's nor EPA's arguments completely persuasive. Instead, it adopted the approach advocated by the Vinyl Institute and held that EPA must engage in a two-step process to establish HAP emission standards. The court held that EPA must first determine an exposure level considered ''safe'' or ''acceptable'' to public health, without taking into account economic and technological considerations.[4] In the second step, however, EPA was required to consider such costs in setting the final HAP standard at a level that provided for an ''ample margin of safety.''

Following the *Vinyl Chloride* decision, EPA incorporated this ''two-step'' methodology into subsequent NESHAPs. The best example of this approach is the 1989 rule governing benzene storage vessels and equipment leaks (the ''benzene NESHAP'').[5] An understanding of this two-step approach is essential because, as discussed below, EPA intends to use the same methodology in setting residual risk standards. In the first step of the analysis, EPA reasoned that its determination of ''acceptable risk'' could not be based on any one factor, but instead, must be based on a variety of considerations, including the risk to an individual who is exposed to the maximum level of a pollutant for his or her lifetime (MIR), the distribution of risks in the exposed population, incidence, the science policy assumptions and uncertainties associated with the risk measures, and the weight of evidence that a pollutant is harmful to health.[6]

EPA began the first step of the analysis by focusing on the MIR. EPA presumed that if the MIR was no greater than one in 10,000, the exposure was acceptable.[7] EPA then adjusted the MIR based on the other health and risk factors described above to complete an overall judgment of the ''safe'' or ''acceptable'' level of risk.[8]

In the second step of the *Vinyl Chloride* analysis, EPA set the level for benzene emissions at a level providing for ''an ample margin of safety'' taking into account health information (such as the number of persons at risk levels higher than one in 1 million), costs, technology, feasibility, and other factors. EPA ultimately set the standard at a level that left the cancer risk no higher than one in 1 million for more than 99 percent of individuals within 50 kilometers of the benzene storage sources. [9]

HAP Emissions Standards After 1990

By 1990, EPA had listed only eight HAPs and established seven NESHAPs.[10] This slow pace of regulation, in part, led Congress to amend the Clean Air Act and revamp the air toxics program. Congress first specifically identified 189 HAPs. While the Agency can modify the HAP list (currently, 188 HAPs are listed), establishing this list authorized EPA to regulate without first proving the kind of health threat necessary to justify regulations under the old Clean Air Act Section 112.[11] Congress then required EPA to publish a list of all categories and subcategories of major sources and ''area'' (minor) sources of the listed HAPs.[12] Finally, Congress required EPA to set emission standards for HAPs from these sources in two phases.

In the first phase of regulation, Congress required EPA to promulgate emissions standards that reduce HAPs at regulated sources to the maximum extent possible taking into account the cost of achieving the emission reduction, any non-air quality health and environmental impacts, and energy requirements.[13] This level of emissions control is commonly referred to as ''maximum achievable control technology'' (''MACT'').

In the second phase, Congress required EPA to develop and issue a report to Congress identifying, among other items, the methods of calculating the remaining risk to public health following the implementation of the MACT standards, the public health significance of such remaining risk and the technologically and commercially available methods and costs of reducing such risk, and the actual remaining health risk to the public following the implementation of the MACT standards.[14] If Congress did not act upon the report within eight years of promulgating a MACT standard for a particular category or subcategory of sources, EPA would be required to promulgate additional emissions limits for each such category or subcategory as necessary to ''provide an ample margin of safety to protect public health in accordance with this section or to prevent, taking into consideration costs, energy, safety, and other relevant factors, an adverse environmental effect.''[15] These emission standards are commonly referred to as the ''residual risk'' standards. In general, Congress left it to EPA to determine what constitutes an ''ample margin of safety.'' For pollutants classified as known, probable, or possible human carcinogens, however, Congress specified that EPA must promulgate a residual risk standard if the MACT standard for any

[1] *Natural Resource Defense Council v. U.S. Environmental Protection Agency*, 824 F. 2d 1146, 26 ERC 1263 (D.C. Cir. 1987).
[2] *Id*. at 1147.
[3] *Id*. at 1147-48.
[4] *Id*. at 1164-65.
[5] 54 Fed. Reg. 38,044, 38,045 (Sept. 14, 1989).
[6] 54 Fed. Reg. at 38,046.
[7] 54 Fed. Reg. at 38,045.
[8] 54 Fed. Reg. at 38,046.
[9] 54 Fed. Reg. at 38,045.
[10] EPA had listed asbestos, benzene, beryllium, coke oven emissions, inorganic arsenic, mercury, radionuclides, and vinyl chloride as HAPs and established NESHAPs for all except coke oven emissions.
[11] 42 U.S.C. § 7412(b)(1).
[12] 42 U.S.C. § 7412(c)(1).
[13] 42 U.S.C. § 7412(d)(2).
[14] 42 U.S.C. § 7412(f)(1).
[15] 42 U.S.C. § 7412(f)(2)(A).

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source category did not reduce the lifetime excess cancer risks to the individuals most exposed to emissions to less than one in 1 million.[16]

EPA Submits Report to Congress

EPA prepared and submitted its *Residual Risk Report to Congress* in March 1999 (referred to herein as the *Residual Risk Report*).[17] Pursuant to Clean Air Act Section 112(f), one of the purposes of the *Residual Risk Report* was to identify the methods EPA would use to calculate the risk remaining to public health after application of the MACT standards.[18]

In summary, the framework described in the *Residual Risk Report* consists of a tiered assessment of the human health and environmental risks resulting from both inhalation and non-inhalation exposures to HAPs following MACT implementation.[19] The *Residual Risk Report* indicates that EPA will separate the assessment into three distinct phases: problem formulation, analysis, and risk characterization.[20] In the problem formulation phase, EPA will specify the content and scope of the risk assessment.[21] In the analysis phase, EPA will evaluate exposure and effects of the pollutant, as well as the relationship between them.[22] Finally, in the risk characterization phase, EPA will estimate and interpret risk through integration of the exposure and effects analyses.[23] EPA expressly stated in the *Residual Risk Report* that it intended to use the benzene NESHAP analysis ''for making final risk management decisions under section 112(f) for carcinogens rather than adopting any single 'brightline.' ''[24]

EPA Proposes Coke Oven Limits

EPA issued MACT standards for coke oven batteries on Oct. 27, 1993.[25] Congress did not act upon any of the recommendations in the *Residual Risk Report* with respect to further standards for coke oven batteries, and therefore, pursuant to Clean Air Act section 112(f)(2)(A), EPA was required to proceed with an examination of residual risk standards for these sources.[26] Accordingly, on Aug. 9, 2004, EPA proposed residual risk standards for coke oven batteries.[27]

EPA initially determined that the risk to the individual most exposed to emissions from coke oven batteries exceeded one in 1 million excess individual cancers.[28] Thus, additional action was required under Section 112(f)(2)(A). EPA then employed a two-step determination of acceptable risk and ample margin of safety, utilizing the same approach set forth in the benzene NESHAP.[29] EPA summarized the objective of that approach as follows:

> . . . in protecting public health with an ample margin of safety, we strive to provide maximum feasible protection against risks to health from hazardous air pollutants by (1) protecting the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million; and (2) limiting to no higher than approximately 1 in 10 thousand [i.e., 100 in a million] the estimated risk that a person living near a facility would have if he or she were exposed to the maximum pollutant concentrations for 70 years.[30]

EPA designed its risk assessment for coke ovens to generate a series of risk metrics that looked at both maximum individual risk and total population risk.[31] To assess inhalation risk, EPA assumed that an individual living within 50 km of each coke facility was exposed to the maximum level of coke oven emissions allowed by the MACT standards and that he or she was exposed to that level of emissions 24 hours a day for 70 years.[32] If risk levels exceeded one in 1 million, EPA then identified the number of people at the various risk levels exceeding one in 1 million, again using the assumption of exposure 24 hours a day for 70 years.[33] EPA also conducted multimedia, multipathway exposure modeling to determine if routes of exposure other than inhalation existed.[34]

EPA noted that, in the benzene NESHAP, it had determined that a MIR of approximately one in 10,000 would ordinarily be the upperbound limit of acceptable risk, although such a level of risk was not necessarily the ''true'' risk, but rather, the ''upper bound that was unlikely to be exceeded.''[35] EPA further stated that the acceptable level of risk should include the MIR when weighed against several health measures and factors.[36]

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[16] 42 U.S.C. § 7412(f)(2)(A).

[17] *Residual Risk Report to Congress*, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, EPA-453/R-99-001 (March 1999).

[18] 42 U.S.C. § 7412(f)(1)(A).

[19] *Residual Risk Report*, p. 31.

[20] *Residual Risk Report*, p. 31.

[21] *Residual Risk Report*, p. 31.

[22] In general, ''exposure'' relates to the likelihood that a pathway will exist through which a person will be affected by a contaminant (e.g., ingestion and inhalation), whereas ''effects'' relates to the consequences the contaminant will have on the exposed person.

[23] *Residual Risk Report*, pp. ES-11, 131.

[24] *Residual Risk Report*, p. 105.

[25] Coke oven batteries are used to produce coke from coal. A typical ''byproduct'' coke oven battery, the more prevalent type of coke oven battery in the United States, consists of 40 to 60 adjacent ovens with common side walls made of high-quality silica and other types of refractory brick. Coal is introduced into the ovens and heated to between 1,650 to 2,000 degrees Fahrenheit in the absence of air to drive off most of the volatile organic constituents of the coal as gases and vapors. The end product is coke, which consists almost entirely of carbon. Coke is primarily used in blast furnaces as fuel and in foundry furnaces for melting scrap iron to produce iron castings. The primary HAPs from this process are benzene, toluene, xylene, polynuclear aromatic hydrocarbons, polycyclic organic matter, and trace metals, notably arsenic. 69 Fed. Reg. 48,338, 48,341 (Aug. 9, 2004).

[26] 42 U.S.C. § 7412(f)(2)(A).

[27] 69 Fed. Reg. at 48,342 (EPA's proposed residual risk emission standards for coke oven batteries apply to each coke oven battery subject to the emission limitations in 40 C.F.R. 63.302 and 40 C.F.R. 63.303 (i.e., the MACT track batteries).

[28] 69 Fed. Reg. at 48339.

[29] 69 Fed. Reg. at 48339-40.

[30] 69 Fed. Reg. at 44,340.

[31] 69 Fed. Reg. at 44,345. Total population risk takes into account the number of people living around the regulated facilities that have potential risk greater than one in a million, the number of people at various risk levels, and the impacts for different routes of exposure. *Id*.

[32] 69 Fed. Reg. at 44,345.

[33] 69 Fed. Reg. at 44,345.

[34] 69 Fed. Reg. at 44,345. EPA's modeling contained the assumption of an adult living on a farm and consuming meat, dairy products, and vegetables produced by the farm, where the animals raised on the farm foraged on farm products, and the adult ate fish caught from nearby waters. *Id*.

[35] 69 Fed. Reg. at 48,348.

[36] 69 Fed. Reg. at 44348.

With respect to coke oven emissions following the 1993 MACT standards, EPA estimated the MIR to be 200 in 1 million (four in 10,000). This was obviously greater than the presumptively acceptable level of one in 10,000 expressed in the benzene NESHAP.[37] However, given consideration of the following factors, EPA determined that such a level of risk was acceptable:[38]

- more than 93 percent of the exposed population had risks less than one in 1 million;
- fewer than eight people in the exposed population had risks exceeding 100 in 1 million;
- the annual incidence of cancer resulting from the limits in the MACT standards was estimated as 0.04 case, or 1 case per 25 years; and,
- facilities were actually emitting at levels lower than the MACT standards, such that the actual risks from those coke ovens were less than those presented for applicable modeling.

Therefore, EPA concluded in the first step of the analysis that risks from coke oven emissions meeting the 1993 MACT standard were ''acceptable'' risks.[39]

EPA then went on to the second step in the process and established a lower standard after considering the costs of implementation, feasibility, technology, and reduction of risk.[40] One control measure that companies can use to achieve the lower limit is a work practice program that includes procedures to identify and seal door and lid leaks, estimated to cost $4,500 per year based on the projected number of leaks to be sealed and a conservative estimate of 30 minutes of labor per leak.[41]

EPA rejected several measures that were found to be unreasonable and/or economically infeasible.[42] For example, EPA rejected imposing leak rates on doors and/or lids that had been achieved by industry most of the time, but due to inherent variability in equipment and processes, could not be achieved at all times by all sources.[43] EPA also considered imposing a more stringent limit on that part of the process where coal is discharged into the coke ovens (known as ''charging''), but ultimately concluded that such a limit would achieve only a negligible reduction in emissions and risk, but increase the potential for noncompliance.[44] Lastly, EPA considered requiring facilities to convert to nonrecovery cokemaking technology (i.e., a process that does not recover the chemical byproducts). EPA concluded, however, that replacing existing batteries with nonrecovery batteries would be financially crippling to the industry (construction of a nonrecovery battery requires a capital investment of approximately $300 per ton of coke capacity—a sum on the order of hundreds of millions of dollars).[45]

Comments Filed in Response to Proposal

EPA received numerous comments on the proposed residual risk standards for coke oven batteries, several of which are summarized below. The number of comments likely reflects recognition by commenters that, although the statutory provisions for coke ovens are different from other sources under Section 112,[46] the principles EPA adopted for coke ovens may serve as the basis for future residual risk standards.[47]

Comments From Residual Risk Coalition. One major industry group, the Residual Risk Coalition,[48] supported many of the actions taken by EPA in setting the benzene NESHAP; consideration of individual and population risk in making regulatory determinations; recognition that cost and feasibility issues may preclude reducing all risks to an ''arbitrary'' risk level such as one in 1 million; and interpretation of the residual risk framework in conjunction with Congress' mandate to revisit the MACT standards every eight years.[49]

The Residual Risk Coalition also voiced several areas of concern regarding the proposed standards. First, the coalition requested that EPA expressly declare that a hazard index level of 1.0 should not be set as a ''bright-

[37] 69 Fed. Reg. at 44,348.
[38] 69 Fed. Reg. at 44345.
[39] 69 Fed. Reg. at 48,348.
[40] 69 Fed. Reg. at 48,348-50.
[41] 69 Fed. Reg. at 48,348.
[42] 69 Fed. Reg. at 48,349 (e.g., EPA rejected requiring replacement of existing batteries with non-recovery batteries).
[43] 69 Fed. Reg. at 48,349.
[44] 69 Fed. Reg. at 48,349.
[45] 69 Fed. Reg. at 48,349.

[46] Congress enacted a unique regulatory regime for controlling HAP emissions from coke ovens. *See* 42 U.S.C. §§ 7412(d)(8), 7412(e)(1)(B), 7412(i)(8). EPA expressly recognized that the residual risk standards for coke oven emissions should not be viewed as precedent by cautioning that ''the methods and policies reflected in the proposed amendments should not necessarily be construed as setting a precedent for future rules under the residual risk program established by section 112(f).'' 69 Fed. Reg. at 48,340.

[47] EPA recently published a proposed consent decree it entered into with the Sierra Club in which it agreed to finalize the coke oven emissions residual risk rule by March 31, 2005 and the dry cleaner emissions residual risk rule by April 28, 2006. In addition to residual risk standards for coke oven and dry cleaner emissions, EPA is currently working on the following 23 residual risk standards: industrial cooling towers, petroleum refineries, hazardous organic NESHAPs (''HON''), gasoline distribution, ethylene oxide sterilizers, magnetic tape, halogenated solvents, chrome electroplating, polymers & resins I, polymers & resins II, polymers & resins IV, secondary lead, aerospace, marine vessel loading, wood furniture, ship building, printing/publishing, off-site waste, flexible polyurethane foam production, mineral wood production, oil and natural gas production, wool fiberglass manufacturing, and ferroalloys production.

[48] The Residual Risk Coalition is comprised of the American Chemistry Council, the American Coke and Chemicals Institute, the American Forest and Paper Association, the American Iron and Steel Institute, the American Petroleum Institute, the Pharmaceutical Research and Manufacturers of America, and the Portland Cement Association.

[49] In its proposed rule, EPA specifically invited the public to comment on EPA's stated interpretation of Clean Air Act section 112(6) and the relationship between sections 112(d)(6) and 112(f). Section 112(d)(6) states: ''[EPA] shall review, and revise as necessary (taking into account developments in practices, processes, and control technologies), emission standards promulgated under this section no less often than every 8 years.'' 42 U.S.C. § 7412(d)(6). EPA does not believe that section 112(d)(6) requires it to analyze MACT floors for new and existing sources every eight years. Rather, EPA believes that section 112(d)(6) requires it to review and revise MACT standards as necessary every eight years, and if it finds relevant changes in practices, processes, and/or control technologies, it can revise the MACT standards. In addition, once residual risk standards are promulgated, EPA questions ''whether further reviews of technological capability are 'necessary' (section 112(d)(6)).'' 69 Fed. Reg. at 48,351.

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line'' level for appropriate risk.[50] It recommended that EPA establish a hazard index level for the lower end of the ample margin of safety range, taking the specific HAPs and the source characteristics into account. Second, the coalition requested that EPA determine whether a residual risk standard is necessary based on the risk presented by the source category under consideration, rather than the risk presented by other sources at the facility and/or from the entire facility. Third, it urged EPA to closely follow EPA's Information Quality Guidelines in establishing residual risk standards. Lastly, the coalition requested that EPA further develop its multipathway and ecological risk assessment methods before they were used in future residual risk rules.

Comments From Industry Task Force. The Coke Oven Environmental Task Force, formed by the American Iron and Steel Institute and the American Coke and Coal Chemicals Institute, agreed with EPA's interpretation that Clean Air Act section 112(d)(6) does not require a ''re-assessment'' of the MACT floor every eight years and that implementation of residual risk standards may obviate the need for any review under section 112(d)(6). However, the task force strenuously disagreed with many of the assumptions EPA used in its risk analysis and submitted two separate risk analyses to highlight the alleged errors. The task force claimed EPA used an outdated cancer unit risk estimate for coke oven emissions; EPA did not account for population mobility in its population risk estimates; EPA did not use an available methodology for estimating microenvironmental exposure; and EPA assumed the existence of subsistence farmers near each of the relevant plants without factual support.

Comments From Environmental Groups. The Natural Resources Defense Council, Earthjustice, and the Sierra Club collectively submitted comments criticizing both the proposed residual risk standards for coke oven emissions and the methodology EPA utilized in establishing the standards. Chief among their comments were the following criticisms:

- EPA's risk analysis ignored HAPs for which it lacked cancer potency values;
- EPA's emission estimates did not account for periods of startup, shutdown, or malfunction;
- EPA did not consider risks posed by co-located sources of coke oven emissions;
- EPA did not consider mercury pollution from coke ovens;
- EPA failed to address acute risks of exposure to HAPs from coke ovens; and
- EPA's risk analysis did not consider multipathway risks adequately.

In addition, the Natural Resources Defense Council, Earthjustice, and the Sierra Club criticized EPA for refusing to set residual risk standards based on the use of nonrecovery technology. They characterized as arbitrary and capricious EPA's belief that such standards would be financially crippling to the industry.

Comments From STAPPA/ALAPCO. The State and Territorial Air Pollution Program Administrators and the Association of Local Air Pollution Control Officials (STAPPA/ALAPCO) noted several concerns with the proposed standards. STAPPA/ALAPCO argued that the proposed standards failed to meet Clean Air Act section 112(f)'s mandate to provide for an ample margin of safety to protect public health because EPA failed to account for fugitive emissions in calculating risk. The group also argued that while EPA had the statutory authority to consider cost of controls when assessing adverse environmental effects, it lacked such authority when considering health-based standards. For future residual risk standards, STAAPA/ALAPCO requested that EPA calculate the cumulative effects of several closely located facilities within the same source category and establish residual risk standards accordingly.

EPA Issues Final Coke Oven Standards

On April 15, 2005, EPA issued final residual risk standards for coke oven emissions.[51] Although the actual residual risk standards imposed on the regulated emissions sources did not change from EPA's proposed residual risk standards, the underlying risk analysis did change somewhat due to EPA's incorporation of revised cancer guidelines issued after the proposed residual risk standards were promulgated on Aug. 9, 2004.

Pursuant to Clean Air Act Section 112(o)(7), EPA was required to issue revised cancer guidelines prior to its promulgation of the first residual risk rule.[52] On March 29, 2005, EPA issued ''Guidelines for Carcinogen Risk Assessment'' (Cancer Guidelines) and ''Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens'' (Supplemental Guidance) to comply with that provision. The Cancer Guidelines, which were last revised in 1986, set forth EPA's recommended principles and procedures designed to guide its scientists and others in assessing cancer risks from exposure to chemicals and other environmental agents. The Supplemental Guidance describes possible approaches that EPA could use in assessing cancer risks for children up to 16 years of age.

In light of the Cancer Guidelines and Supplemental Guidance, EPA revised the risk assessment used in development of the proposed residual risk standards.[53] EPA utilized the Supplemental Guidance's default ''age dependent adjustment factors,'' which can be applied when assessing cancer risk for early-life exposures to chemicals that cause cancer through a mutagenic mode, as EPA claims is the case with coke oven emissions.[54] The revised risk assessment resulted in an increase of individual and population cancer risk estimates for lifetime exposures that begin at birth and extend through adulthood by a factor of 1.6 from that used in development of the proposed residual risk standards.[55]

[50] The hazard index is the sum of hazard quotients for hazardous air pollutants that target the same organ or system, where a hazard quotient is calculated as the ratio of the exposure concentration of a pollutant to its benchmark concentration. 69 Fed. Reg. at 48,345. The Residual Risk Coalition is concerned that, based on the wording of one paragraph in the proposed rule, some individuals will interpret EPA's risk analysis to mean that the ''acceptable risk level'' for the coke oven category was set at a hazard index of 1.0.

[51] 70 Fed. Reg. 19,992 (April 15, 2005).
[52] 42 U.S.C. § 7412(o)(7).
[53] 70 Fed. Reg. at 19,993.
[54] *Id.*
[55] *Id.*

The resulting MIR estimate increased from 200 in 1 million as calculated in the proposed residual risk standards risk analysis to 300 in 1 million.[56] EPA then applied the default adjustment factor to other analyses that were used to support the previous determination that the MIR estimate of 200 in 1 million was acceptable, which resulted in the following analysis conclusions:[57]

- more than 88 percent of the exposed population had risks less than one in 1 million;
- approximately 70 people in the exposed population had risks exceeding 100 in 1 million; and
- the annual incidence of cancer resulting from the limits in the MACT standards was estimated as 0.06 case.

EPA cautioned that, although it was adjusting risk estimates upward to reflect the new guidance, the estimated risk increases should be tempered by consideration of other factors, such as the following:[58]

- Built into the risk assessment is a protective assumption that all individuals are born in the assessed area.
- Coke oven battery sources are consistently controlling emissions below the level allowed by the 1993 MACT standards, which, if taken into account, would result in a 30 percent reduction in the MIR estimate.
- The risk assessment used a health-protective assumption of a 70-year exposure duration whereas the estimate of risk would be reduced by a factor of six if the national average residency time of 12 years were used.
- EPA's 70-year exposure assumption includes exposures from birth to 70 years.

[56] *Id.*
[57] *Id.* at 19,993-94.
[58] *Id.* at 19,994.

After considering all of these factors, EPA considered the estimated MIR of 300 in 1 million due to emissions at the limits in the 1993 MACT standards to be an acceptable level of risk.[59]

EPA then proceeded to the next phase of the two-step analysis, calculating the level of control necessary to provide an ample margin of safety to protect human health.[60] It estimated that the proposed residual risk standards would reduce the estimated MIR from exposure to coke oven emissions to 270 in 1 million.[61] Without further explanation, but referring to its discussion in the proposed rule preamble, EPA concluded that the proposed residual risk standards provide an ample margin of safety to protect public health and adopted them as the final standards.[62]

Conclusion

The residual risk standards for coke oven emissions represent EPA's first health-based emission standards under Clean Air Act section 112(f). In setting these standards, EPA used the two-step determination of acceptable risk and ample margin of safety that it utilized in establishing the benzene NESHAP. In general, industry commentators did not oppose that approach or the result that EPA achieved with respect to the actual standards themselves. Rather, they objected to the manner in which EPA secured and utilized data in its risk analyses, the assumptions EPA used in the risk analyses, and other aspects of EPA's risk assessment. Environmental groups opposed both the methodology EPA utilized to set the residual risk standards and the standards themselves.

[59] *Id.*
[60] *Id.*
[61] *Id.*
[62] *Id.*

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