Coalition for Responsible Waste Incineration

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October 8, 2004

National Emission Standards for
Coke Oven Batteries Docket
Environmental Protection Agency
Mail Code: 6102T
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Attn: Docket ID No. OAR-2003-0051

The Coalition for Responsible Waste Incineration (CRWI) appreciates the opportunity to submit comments on EPA's proposed National Emission Standards for Coke Oven Batteries, 69 Fed. Reg. 48338 (August 9, 2004). CRWI is a trade association comprised of 26 members with interests in air emission regulations. All of our members are regulated by MACT standards under Section 112 of the Clean Air Act and are subject to EPA's authority under the residual risk provisions in section 112(f). We appreciate the effort EPA has put into promulgating this groundbreaking proposal.

Detailed comments are attached. If additional information is needed or desired, please contact us at 202-452-1241 or crwi@erols.com.

Sincerely yours,

Melvin E. Keener, Ph.D.
Executive Director

cc: CRWI members
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Comments of the
Coalition for Responsible Waste Incineration
On
EPA's Proposed Residual Risk Rule for Coke Oven Batteries,
National Emission Standards for Coke Oven Batteries;
Proposed Rule
69 Fed. Reg. 48338 (August 9, 2004)
Docket No. OAR-2003-0051

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## Executive Summary

In general, CRWI commends the Agency on a majority of the proposal. In particular we support:

1. EPA adopting the two-step approach for setting standards it enunciated in the Benzene NESHAP rule.

2. EPA interpreting the statute as establishing a one in a million risk level for triggering rulemaking, but not making this level the standard that must be achieved to satisfy the statute's command to supply an "ample margin of safety" (AMOS). Instead, EPA states that this risk level is a goal to be assessed considering costs and other factors.

3. EPA using population risk estimates to set the standards.

4. EPA using a "target organ" approach when considering non-cancer risks.

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5. EPA deciding that they are not required to redo the MACT floor when conducting 8-year MACT reviews under Section 112(d)(6). Instead, CRWI suggests that EPA must determine that "developments" have occurred on practices, processes, and control technology, in order to revise the rules.

6. EPA deciding that after it makes a residual risk determination and promulgates a rule, no more revisions to the technology standards are necessary.

The Coalition also has a number of concerns about the Agency's proposal.

- EPA performed its risk assessment using the emission rate allowed by the technology-based standards, rather than the rates the standards cause facilities to emit. As EPA notes, it is rare that a facility will release maximum allowable emissions all the time, and this approach "overstates actual emission levels." 69 Fed. Reg. at 48346. EPA adopted this approach based on statutory language that CRWI believes should be interpreted differently.

- EPA based its risk assessment on unrealistic assumptions including the presumption that individuals will be exposed to the highest allowable emissions 24 hours a day for 70 years. This means that the Agency's risk assessment will always be overly conservative and trigger the need for additional, and unnecessarily stringent, standards more frequently than necessary. CRWI asserts that the statute supports EPA adopting more realistic assumptions.

- EPA indicates that it will consider the risks from all sources rather than risks from just the source category being regulated. This approach contradicts the plain words of the statute and is unworkable.

- EPA proposed that coke ovens make further emission reductions to ensure an "ample margin of safety" even though the actions they are requiring may not produce discernible results. CRWI submits that it is not good policy to require additional reductions if the Agency cannot be sure that they will result in any benefit — regardless of how cost-effective or inexpensive the additional reductions are to implement. EPA should first determine whether there are discernible benefits from any further regulation before it decides to examine the cost of achieving it.

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- EPA does not state that the $1 \times 10^{-6}$ level is a limit on their regulatory authority for controlling carcinogens. The statute clearly states that additional reductions are not required unless risks exceed this level.

- EPA used a Hazard Index of 1.0 as "ordinarily" representing the "acceptable level" for non-carcinogens. This level should not be equated with what constitutes an acceptable level. Instead, a Hazard Index of 1.0 should be the most stringent expression of what constitutes an ample margin of safety.

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Coalition for Responsible Waste Incineration
On
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69 Fed. Reg. 48338 (August 9, 2004)
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# I. Introduction

The Coalition for Responsible Waste Incineration (CRWI) appreciates the opportunity to submit comments on EPA's proposed National Emission Standards for Coke Oven Batteries, 69 Fed. Reg. 48338 (August 9, 2004). CRWI is a trade association comprised of 26 members with interests in air emission regulations. All of our members are regulated by MACT standards under Section 112 of the Clean Air Act and are subject to EPA's authority under the residual risk provisions in section 112(f). We appreciate the effort EPA has put into promulgating this groundbreaking proposal.

This is the Agency's first effort to establish risk-based regulations for hazardous air pollutants using its revised authority under the Clean Air Act. When Congress enacted the air toxics program in 1977, it required EPA to determine which air pollutants were toxic, where they were coming from, and how to set risk-based limits that were protective of human health with an "ample margin of safety." By 1990, however, EPA had set standards for only 8 pollutants. Congress, therefore, revised the program to remove some of the impediments to regulation. They created the list of hazardous air pollutants to be regulated, directed EPA to set standards for industrial source categories consistent with the list developed for new source performance standards and, rather than risk-based standards, required EPA to set technology-based standards that reflected what the best performing sources could achieve.

Congress did not jettison the risk-based approach completely, however. Indeed, it retained the original purpose of the previous provisions. It just changed the timing for promulgating risk-based rules. Because technology-based standards may, or may not, protect human health and the environment, Congress directed EPA to review the degree of risk that remained after their implementation and promulgate additional regulations if necessary.

But, Congress did not know whether, or how, to revise the risk-based provisions in a way that removed remaining impediments to EPA promulgating these regulations. In the few years before passage of the 1990 amendments, the D.C. Circuit Court of Appeals had provided the Agency with its interpretation of the previously enacted risk-based provisions and on September 14, 1989, EPA had promulgated the Benzene NESHAP rule based on the court's opinion.

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Consequently, Congress was hopeful EPA had, at last, figured out how to implement the risk-based standard setting provisions. Therefore, Congress directed EPA to study the issues surrounding implementation of its authority and write a report making legislative recommendations. In that way, Congress could give EPA the tools it needed so the Agency could successfully proceed with the risk-based component of the program. If Congress failed to act on the Agency's recommendations, then EPA was to proceed with setting risk-based standards using the criteria and methodologies they used in the Benzene NESHAP rule.

In 1999, EPA presented its Residual Risk Report to Congress without any legislative recommendations. Thus, no legislative changes were made and EPA was left to implement the section as recreated in 1990.

While the Agency notes that the statute contains special provisions regarding coke ovens and this rule "should not necessarily be construed as setting precedent for future residual risk rules," 69 Fed. Reg. at 48340, EPA's proposal makes basic decisions about how the Agency will implement the residual risk provisions. In particular, the Agency publishes, for the first time, how it plans to implement the principles contained in the Benzene NESHAP, the rule that Congress wanted the Agency to follow. In addition, EPA sets forth its long-held view that it has discretion to decide that risks greater than $1 \times 10^{-6}$ can represent an ample margin of safety (AMOS). Finally, EPA conducted a risk assessment and AMOS determination using the two-step process enunciated by the D.C. Circuit Court of Appeals and implemented in the Benzene NESHAP using new tools and methods that have been developed over the past 15 years.

## II. CRWI Supports EPA's Overall Approach in This Rule.

While Congress has not provided any additional guidance on how to implement the residual risk standards, EPA has guidance from other sources. In 1987, the D.C. Circuit Court of Appeals reviewed the Agency's rule regulating vinyl chloride emissions under the previous incarnation of section 112. In that decision, *NRDC v. EPA*, 824 F.2d 1146 (D.C. Cir. 1987), the Court informed the Agency that the statute contained a two-step process for establishing standards that are protective of human health with an ample margin of safety. The first step should be to determine what level is protective. Afterwards, EPA should look at the scientific uncertainties and other factors, to determine what constitutes an ample margin of safety. *Id.* at 1165.

After the court's decision, the Agency promulgated the Benzene NESHAP rule which interpreted and implemented that court decision. 54 Fed. Reg. 38044 (September 14, 1989). (NESHAP stands for "National Emission Standards for Hazardous Air Pollutants."). In that rule, EPA expressly adopted the two-step process, and stated that it would generally seek to provide protection at a $1 \times 10^{-6}$


risk level to as many persons as possible. Nonetheless, based on costs and other factors, EPA decided that less stringent protection levels represented an ample margin of safety. Congress expressed its approval for that rulemaking by stating that EPA is required to determine if the technology-based standards "provide an ample margin of safety to protect human health in accordance with this section (as in effect before November 15, 1990)." CAA § 112(f)(2)(A). Consequently, Congress wanted EPA to follow the principles in that rule.

That is what EPA has done in this rule. As discussed in the preamble, EPA has adopted the two-step approach for setting standards it enunciated in the Benzene NESHAP rule. It requires them, first, to determine what constitutes an "acceptable level" of risk and then decide what constitutes an "ample margin of safety." 69 Fed. Reg. at 48339 – 40.

### A. EPA Has Properly Construed The Statute As Establishing A Trigger For Regulating Carcinogens and Not As Setting a Standard That Must Be Achieved.

The residual risk standard-setting provision Congress enacted in 1990 is only three sentences long yet, at first blush seems redundant, and can be confusing. The first sentence is a trigger for rulemaking. It tells EPA that if Congress does not act on any of EPA's recommendations, then the Agency shall proceed to set emission limitations within eight years after promulgation of the technology-based standard for each source category[1] — if limits are necessary to protect human health with an ample margin of safety or to prevent an adverse environmental effect. EPA promulgated the technology-based standard for this group of coke oven emissions in 1993.

The next sentence is a standard setting provision. It tells EPA that any emission standard it promulgates under the residual risk provisions must be protective of human health and the environment with an ample margin of safety — in accordance with the approach EPA devised before passage of the Clean Air Act Amendments of 1990 — unless the Administrator determines that a more stringent standard is necessary to prevent adverse environmental effects.

The third sentence, which originated in the Senate Bill, relates to risks from carcinogenic pollutants and is a key sentence for this rulemaking since many of the HAPs emitted by coke ovens are carcinogenic. The sentence, which is written as an "if, then" statement reads:

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[1] Later provisions give EPA nine years to promulgate residual risk standards for those source categories that were in the 2-year bin.

> If standards promulgated pursuant to subsection (d) of this section and applicable to a category or subcategory of sources emitting a pollutant (or pollutants) classified as a known, probable or possible human carcinogen 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, the Administrator shall promulgate standards under this section for such source category.

This means that if the risk from one source is greater than a $1 \times 10^{-6}$ excess cancer, then EPA must proceed to setting standards. Those standards, however, are to be set under the authority of the second sentence and using the process described in the Benzene NESHAP rule, *i.e.*, determining an "acceptable level" of emissions and then examining cost and other factors to determine what degree of regulation constitutes an ample margin of safety. EPA is not required to provide protection that achieves the one in a million excess cancer level.

Accordingly, CRWI believes that EPA has properly interpreted this provision as a separate rulemaking trigger for carcinogens and not as a standard that must be achieved by the Agency's regulations. 69 Fed. Reg. at 48339 – 40.

This interpretation is corroborated by other provisions in the statute. In particular, when setting up the schedule for establishing residual risk provisions, Congress wrote in Section 112(f)(2)(C) that:

> (C) The Administrator shall determine *whether or not* to promulgate such standards and, if the Administrator decides to promulgate such standards shall promulgate the standards 8 years . . ..

Thus, EPA should examine the need for rules using (1) the non-carcinogenic trigger of what constitutes an ample margin of safety, (2) whether the technology-based standards are stringent enough to avoid an adverse environmental effect, or (3) whether the standards are allowing people to be exposed to emissions from the category in question at a level that exceeds a one in a million excess cancer level. If so, then EPA should proceed to establish more stringent regulations to provide that ample margin of safety or avoid the adverse environmental effect. That is what EPA did in this rule. After determining that one source presented risks greater than $1 \times 10^{-6}$, EPA then proceeded to determine whether or not to promulgate a standard by first determining what degree of risk was "acceptable" and then establishing an ample margin of safety. Like the Agency did in the Benzene NESHAP, the AMOS level was less stringent than $1 \times 10^{-6}$.

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### B. CRWI Supports EPA's Use of Population Risk and Uncertainty Analysis to Set the AMOS Level.

In the coke oven rule, EPA decided to propose a standard that protected the individual most exposed to a level that equated with $1.4 \times 10^{-4}$ excess cancer cases. EPA noted that "In making this determination, we considered the estimate of health risk and other health information along with additional factors relating to the appropriate level of control, including costs and economic impacts of controls, technological feasibility, uncertainties and other relevant factors." 69 Fed. Reg. at 48348.

CRWI supports EPA considering these other factors and in particular the Agency considering population risk and the conservatism of its risk assessment. EPA considered both of these factors in the Benzene NESHAP rule and accordingly, it was appropriate to consider them here.

#### 1. EPA Appropriately Considered Population Risk When Setting Standards That Provide An Ample Margin of Safety.

Rather than exclusively relying on the estimated cancer risk posed to the individual who is most exposed to coke oven emissions, EPA examined the risks to the affected population within 50 kilometers. In the Benzene NESHAP rule, EPA decided that it would not be solely driven by estimates of individual risk. It would, instead, strive to protect "the greatest number of persons possible to an individual lifetime risk level no higher than approximately 1 in 1 million . . .." 54 Fed. Reg. at 38044. Consequently, population risk was an important factor that formed the foundation of its entire methodology for determining both the acceptable level and the ample margin of safety. EPA stated:

> The EPA also considers incidence (the numbers of persons estimated to suffer cancer or other serious health effects as a result of exposure to a pollutant) to be an important measure of the health risk to the exposed population. Incidence measures the extent of health risk to the exposed population as a whole, by providing an estimate of the occurrence of cancer or other serious health effects in the exposed population. The EPA believes that even if the MIR [maximum individual risk] is low, the overall risk may be unacceptable if significant numbers of persons are exposed to a hazardous air pollutant, resulting in a significant estimated incidence. Consideration of this factor would not be reduced to a specific limit or range, such as the 1 case/year limit included in proposed Approach B, but estimated incidence would be weighed along with other health risk information in judging acceptability.

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*Id.*

In the coke oven rule, the Agency's population risk estimate showed that more than 95% of the population would be subjected to cancer risks less than 1 x $10^{-6}$. In addition, EPA's population risk analysis revealed that the existing technology-based standards would result in an annual excess cancer incidence of only 0.04 cases or 1 in every 25 years, and that the ultimate standard based on AMOS, would produce an incidence of only 0.02 cases per year. Thus, by protecting more than 95% of the population to less than this risk level, EPA has adopted a rule that is consistent with the Benzene NESHAP rule.

### 2. EPA Appropriately Considered Other Factors To Determine What Degree of Control Constituted An Ample Margin of Safety.

Along with population risk, EPA also considered the assumptions and estimation uncertainties associated with the risk assessment. EPA concluded that based on its analysis, "the average excess lifetime cancer risks for individuals in the modeled population are likely to be about six times *less* than we predicted." 69 Fed. Reg. at 48347. (Emphasis added.) For example, in the risk assessment EPA assumed that the individual most exposed would be subjected to the maximum emissions 24 hours/day for 70 years. Based on its analysis EPA concluded that the number of people exposed to risk levels greater than 1 x $10^{-4}$ "could be as low as 0." *Id.* Thus, the degree of protection will be much greater than EPA estimates. CRWI believes that it is appropriate to consider the conservative nature of the risk assessment and its estimation uncertainties as part of the Agency's AMOS determination.

## C. CRWI Supports EPA Using a Target Organ Approach When Considering Non-Cancer Risks.

EPA endorses use of a "target organ" approach when considering non-cancer risks. 69 Fed. Reg. at 48345. This means that EPA accounted for exposures from multiple HAPs only if they attacked the same organ. This is consistent with good science and proper risk assessment techniques.

According to the National Research Council and the Commission, additivity at low doses is more likely to overestimate than to underestimate total risk. As the Presidential/Congressional Commission on Risk Assessment and Risk Management stated:

> When the individual components of a chemical mixture exhibit different kinds of toxicity or have different biological mechanisms of

> toxicity, they do not interact -- they act independently at low doses. In that case, the dose-response relationships for each chemical should be considered independently. For example, if the chemicals of concern at a Superfund site are copper, a gastrointestinal toxicant; lead, a development toxicant; and heptachlor, a neurological toxicant, their toxicity should be evaluated independently and not combined into a single "non-cancer" risk estimate. Experiments have shown that when groups of unrelated chemicals with unrelated targets of toxicity were administered to rodents simultaneously at doses equal to their separate NOAELs, no cumulative effects were observed; each chemical acted independently (Jonker et al. 1990, Groten et al. 1994). The same is true of groups of chemicals with the same target but different mechanisms of action (Jonker et al. 1993); studies in which similar chemicals with similar mechanisms and targets were administered simultaneously indicate that antagonism is the usual outcome (Falk and Kotin 1964, Schmahl et al.1977).

Commission Report at 71.

In addition, as EPA knows, reference concentrations that are used to establish risk levels for non-carcinogenic pollutants are based on effects to the most sensitive target organ. Consequently, the metric that EPA uses to evaluate risk from non-carcinogenic pollutants and the weight of scientific authority supports summing exposures only where the primary effect is on the same target organ and occurs by the same mechanism of action.

### D. Before The Agency Can Revise The Technology Based Standard, It Must Find That "Developments" In Practices, Processes, or Control Technology Have Occurred.

The statute requires EPA to set residual risk standards within either eight or nine years after promulgation of the technology-based standards depending on when EPA was required to promulgate the technology-based standards. CAA § 112(d)(2)(C). The statute then requires EPA to review the technology-based standards every eight years. Section 112(d)(6) states, "The Administrator shall review, and revise as necessary (taking into account development in practices, processes, and control technologies), emission standards promulgated under this section no less often than every 8 years." Consequently, the Agency is proposing policy regarding section 112(d)(6) and its intersection with the residual risk provisions in section 112(f)(2).

First, the Agency lays out principles on how to implement Section 112(d)(6). EPA is taking the position that it does not need to conduct a MACT floor analysis

to determine when it is "necessary" to revise the technology-based standards. 69 Fed. Reg. at 48350 – 51. CRWI supports the Agency in this position. In fact, CRWI asserts that, instead of performing a MACT floor analysis, EPA must make a determination that some kind of development has occurred in pollution control practices, processes, or technology[2] in order to trigger a revision of the existing standards.

Second, the Agency is announcing that it should determine whether to revise the rules by considering the impact that the new standards would have on costs, non-air quality effects, and energy usage and production. CRWI also supports that position. Once the Agency determines that a "development" has occurred, it must then proceed to determine if it is necessary to revise the rules. Since the revisions should be consistent with the overall intent of the statute, using the criteria from Section 112(d)(2), which establishes the criteria for the technology-based rules, makes sense.

Finally, the Agency is requesting comment on whether revisions to the technology-based standards are required once the Agency has promulgated residual risks under Section 112(f)(2). CRWI thinks not. We address all three of these issues below.

### 1. EPA's Authority to Revise MACT Standards Is Triggered By a "Development" In Practices, Processes, or Control Technology, And Not By a Revised MACT Floor Analysis.

In the preamble, EPA states that it does not need to re-determine the MACT floors when deciding whether to revise the technology-based limit. 69 Fed. Reg. at 48350 – 51. CRWI believes that position is clearly correct. The statute does not state that the Agency must redo the MACT floor and Congress could have easily said so by cross-referencing the floor provisions in Section 112(d)(3). As EPA notes in the preamble, such a re-determination would amount to a continual lowering of the emission standards that would turn the existing source standards into new source standards. Indeed, the statutory provision is neutral on whether

[2] The Agency might disagree with this characterization since the word "control" is only used when referring to "technologies" and not to practices and processes. We believe that developments in practices and processes must have an affect on actual emissions before they are relevant to the question of revising the MACT standards. This is consistent with the principles that the D.C. Circuit has set forth regarding the MACT standards, *i.e.*, when EPA sets emission standards, it must look at the practices and processes that are affecting emissions. *CKRC v. EPA*, 255 F. 3d 855 (D.C. Cir 2001)


the standards are to be made more stringent or, because of new developments relating to scarcity of materials, or processes, the standards could be relaxed.

But more to the point, using a floor re-determination as the basis for deciding whether revisions are necessary would be unlawful: it would cause EPA to revise the MACT standard even though there was no development in control practices, procedures or technology. This is clearly inconsistent with EPA's statutory authority.

Congress empowered EPA to revise the rules as necessary considering ""developments in practices, processes, and control technologies." Thus, if there are no "developments" that affect the emission levels that can be achieved by the facilities in the source category, then no revisions could be "necessary."

Indeed, not considering "developments" as a predicate for revising the rules means that Congress, in § 112(d)(6), simply told EPA to decide what was necessary based on criteria the Agency develops. This amounts to a standard-less delegation of authority that requires EPA to supply its own decision rules. EPA knows that it cannot do that. *Whitman v. American Trucking Association* 121 S.Ct. 903 (2001). Consequently, unless EPA finds that there have been "developments" it cannot revise the MACT standards.

### 2. EPA Has The Authority To Establish Criteria To Determine Whether Developments In Control Technology, Practices, or Technologies Make It Necessary To Revise The MACT Rules.

Once the Agency's authority to revise the standards has been triggered, the statute lets EPA determine the criteria that makes revising the standards necessary. EPA suggests that they are same criteria the statute sets out for establishing beyond the floor standards. This is appropriate because it is consistent with the Congressional standards for setting technology-based standards. Consequently, EPA should evaluate the cost, non-air quality impacts and energy implications of recent developments in practices, processes, and control technologies, to determine whether changes in the rule are necessary. These changes could make the rules more stringent or less stringent.

### 3. Once EPA Implements the Residual Risk Provisions, Revisions to the Technological Standards Are No Longer Necessary

Finally, the Agency also solicits comments on the relationship between § 112(d)(6) and the residual risk provisions in Section 112(f). 69 Fed. Reg. at 48351. The Agency opines that once the Agency implements the residual risk


provisions, then no further revisions to the technical standards are "necessary." This is clearly correct.

Like the regulatory framework Congress enacted for the previous air toxic program — that Congress wants EPA to continue following — the current version of Section 112 is designed to protect human health and the environment. Consequently, it is risk-based. The technology-based standards are a method toward ensuring that reductions would be achieved while the Agency studied how to implement the risk-based provisions and seek Congressional assistance if needed. Therefore, once EPA promulgates standards that are protective of human health (with an ample margin of safety) and does not cause adverse environmental effects, further revisions to the technology-based regulations are not necessary — Congress' mandate has already been achieved. As Congressman Bliley noted regarding section (c)(4) — a provision that is like Section 112(f) because it deals with rule promulgated under the prior version of the statute,

> No health benefit would flow from requiring EPA to promulgate new section 112 standards for sources that are meeting standards that provide an ample margin of safety under existing NESHAPS. Accordingly, because of this, section 112(c)(4) authority should be utilized only if the applicable standard needs to be revised.

See "A Legislative History of the Clean Air Act Amendments of 1990." (S. Prt. 103-38, Vol. 1, page 1225).

## III. CRWI Has Concerns with EPA's Approach to the Following Residual Risk Issues.

While CRWI believes that EPA's overall approach to the coke oven residual risk rule is sound, we have concerns with several of the more methodological decisions EPA has made toward setting residual risk standards. These include:

- EPA using the emission rate allowed by the technology-based standards to evaluate risk rather than the rates actually being emitted.

- EPA continuing to use unrealistic assumptions in its risk assessment such as the supposition that individuals will be exposed to the highest allowable emissions 24 hours a day for 70 years. While this approach may be useful when doing a "screening" risk assessment, EPA should not make these


assumptions when conducting "refined" risk assessments that result in facilities expending resources.

- EPA indicating that it will consider the risks from all sources at the facility when assessing risks rather than risks from just the source category. This position is unlawful and unworkable.

- EPA proposing that facilities make further emission reductions to ensure an "ample margin of safety" even though the actions they are requiring may not produce discernible results.

- EPA using a Hazard Index of 1.0 as "ordinarily" representing the "acceptable level" for non-carcinogens. Because of the multiple layers of conservatism that are applied to the toxicological values used to calculate the Hazard Index, an H.I. of 1.0 should not be representative of the "acceptable level." Instead it should be the most stringent AMOS level the Agency would adopt.

Our more detailed comments on these issues follow:

**A. EPA Should Use More Realistic Emission Rates When Evaluating the Protectiveness of the Technology-Based Standard.**

In the preamble, EPA states that, when performing its risk assessment, the Agency modeled emissions at the rate allowed by the MACT standards rather than actual emission rates, because this policy is consistent with the language in section 112(f)(2). That provision states:

> If *standards* promulgated pursuant to subsection (d) [MACT standards] * * * do not reduce lifetime risk * * * to less than one in one million, the Administrator shall promulgate standards under this subsection.

(Emphasis supplied.) Consequently, the Agency believes it is compelled to evaluate residual risk based on every facility continually emitting the maximum allowable emissions. However, it is rare, as the Agency notes, that a facility will operate in a way where their average emissions equate to the standards because it would mean that they would be in violation a significant period of time. 69 Fed. Reg. at 48347. Based on the Agency's own analysis, the average excess lifetime cancer risks for individuals in the modeled population are likely to be about 6 times *less* than predicted. *Id.*


CRWI believes that the Agency is not compelled to evaluate residual risk based on continuous maximum emissions from these facilities. Instead, we believe that the Agency should take into account the level of actual emissions when examining whether the technology-based standard is protective. This interpretation is consistent with the statute because Congress meant for EPA to make realistic estimates of remaining risk. This is most evident by Congress' choice of words surrounding the targeted individual. Congress eschewed labeling the targeted individual as the "maximally exposed individual" (MEI), which is commonly understood as a measure of risk to a hypothetical individual,[3] or requiring EPA to determine "maximum individual risk" (MIR) which the Agency used in the Benzene NESHAP and defined as

> the estimated risk of contracting cancer following a lifetime exposure at the maximum, modeled long-term ambient concentration of a pollutant * * *. It is an estimate of the upperbound of risk based on conservative assumptions, such as continuous exposure for 24 hours per day for 70 years. As such, it does not necessarily reflect the true risk, but displays a conservative risk level which is an upperbound that is unlikely to be exceeded.

54 Fed. Reg. at 38045.

Instead Congress decided on a different metric to judge protectiveness. They directed EPA to measure risks to the "individual most exposed to emissions from a source." This choice of words is significant for three reasons. First, Congress was trying to get away from the term maximally exposed individual (MEI) or MIR which had unrealistic connotations. Second, Congress was telling EPA to only consider the risks from a real source in the category. Thus, they wanted EPA to be more realistic.

In fact, during the debate of the Senate bill, which contained provisions relating to how EPA should address carcinogens (the House Bill did not address this issue), Senator Symms introduced an amendment designed to address the overly conservative nature of the risk assessment process as explained in the Committee Report. Senator Baucus, who was the Democratic floor manager, explained that since passage of the bill in Committee (which adopted a dual standard of protecting everyone to a $1 \times 10^{-4}$ level and the individual most exposed to a level of $1 \times 10^{-6}$), they had been negotiating with the Administration

[3] For a discussion of these various terms, see EPA's Residual Risk Report To Congress, EPA 453/R-00-001, at 45 (March 1999).


to make the risk assessment process in the bill more realistic. Senator Baucus explained:

> We worked long and hard on the residual risk section of the bill. The residual risk section was probably debated more, discussed more, in our discussions with the five or six Republican Senators and five or six Democratic Senators, and representatives from the administration, more than any other section of the bill. I would say 30 to 40 percent of our discussions were on this very title, the air toxics, particularly residual risk section of the air toxics portion of the bill.
>
> Because of those discussions, we have greatly modified the provisions as they were reported out of full committee.
>
> The residual risk section the air toxics title as reported out of the full committee essentially stated that after a plant enacted maximum achievable control technology, which by the way would account for at least 90 percent reduction of air toxics that would be emitted from plants, and after installation of that technology, if there was a residual risk of cancer then a plant would have to begin to install technology which would reduce the risk . . ..
>
> That is, if after installing a technology, a plant would still allow a theoretical person, the maximum exposed individual standing next to the plant, 1/10,000$^{th}$ chance of cancer, then the plant would have to shut down.
>
> * * * * *
>
> When we started this section of the discussions, we realized that that was a little too theoretical. That is, it probably made more sense for us to apply that standard, 1 out of 10,000 to an actual person at the plant site; not the theoretical person, but the actual person. So we moved in our discussions away from the theoretical person to the actual person; that is who is this actual person standing near the plant? How exposed would that actual person be?
>
> In addition, we should probably make this site specific. There are some plants where air currents are predominant in one direction; other plants where they are not predominant. There are some plants which are located in populous areas; there are other plants

> which are located in unpopulous areas. We should be more site-specific. That is, what as a practical matter would be cancer risk be to an actual person standing near an actual particular site? That seemed to make more sense. So we moved in that direction, and we adopted that change in our discussions.
>
> We even went further than that and began to ask who is this person standing near the site? Is it a person who in fact lives there for 70 years, which is the theoretical maximum exposed individual standard, or do most people not live 70 years in the same home; do people move sometimes? We tried to take account of that the best we can.
>
> So we modified the standard so that EPA would determine what are the population trends in this community; do the people tend to stay, tend to move? Let us be more actual as best we possibly can; nothing too theoretical about this. So we adopted that standard as well.

Legislative History, Vol. 4 at 5244 – 46.

Senator Symms, however, was not satisfied and again offered his amendment which was tabled. In responding to that effort Senator Baucus said:

> Mr. President, I do not know what bill the Senator is referring to. It is not this bill. The standard in this bill is not this theoretical maximum exposed individual. It is not the theoretical risk that the writer of this amendment contemplates in his amendment. The standard in the bill is actual man, and it is site-specific. It is not at all what the Senator from Idaho seems to think.

*Id.* at 7008.

The bill that ultimately passed Congress, did not contain the exact language passed by the Senate. However, it did direct EPA to consider that individual who is "most exposed to emissions from a source" and not the MEI as Senator Symms feared. As Senator Baucus stated during the debate on the Conference Report of both houses:

> This bill, therefore, provides a safety net for residual risk. The bill requires that if after MACT is in place, a significant risk remains, EPA must tighten the standards 8 years after the initial promulgation of the MACT standard. This directive requires EPA to


> set "residual risk" standards for pollutants that may cause cancer whenever the risk is greater than one in a million to the person in the general population most exposed to emissions from a source in the category."

Legislative History, Vol. 1 at 1030. This means that Congress wanted EPA to determine risk based on real exposures from sources in the category, and not assume that standards, written on paper, were presenting risks.

Consequently, CRWI believes that the language in the third sentence of section 112(f)(2), should be interpreted to mean that EPA should use the actual levels emitted, or if that data is not available to the Agency, the level that the standards cause facilities to operate at in order to consistently comply with the standard, rather than the maximum amount of allowable emissions.

In this rule, EPA had this information. EPA stated:

> The risk analysis assumed that all emission points from the batteries are leaking or emitting at the maximum rate allowable under the 1993 national emission standards for charging, doors, and topside leaks, since it is theoretically possible that these amounts of emissions could occur. However, this assumption (although theoretically possible) overstates actual emission levels. We analyzed 1,000 to 2,600 daily compliance determinations for each battery to compare the actual average emissions to the maximum rate allowed under the 1993 national emission standards as modeled. The results of this analysis indicate that average performance is better than the current MACT limits and is closer to the more stringent 2010 LAER limits. The five MACT track batteries average 44 percent of the MACT limit for doors leaks, 16 percent of the limit for lid leaks, 21 percent of the limit for offtake leaks, and 27 percent of the limit for charging. An average performance that is better than the limit is to be expected because if batteries were to operate on average at the level of the 1993 national emission standards, they would likely exceed the standards a high percent of the time. Consequently, facility owners and operators consistently operate below the standards to avoid violations.

69 Fed. Reg. at 48346 (footnote omitted).

Therefore, EPA should use this emission information as the basis for its risk assessment.

Coalition for Responsible Waste Incineration

### B. EPA's Refined Risk Assessment Should Use More Realistic Exposure Assumptions.

In addition to basing the risk assumption on actual emissions or a reasonable fraction of the standards, EPA should also revise the assumptions pertaining to potential exposure. For this rule, EPA assumed that the "individual most exposed" was being exposed 24 hours/day for 70 years. That, of course, is impossible and further compounds the conservative nature of the risk assessment contrary to Congressional intent as noted above. While the Agency frequently uses such conservative assumptions in screening level risk assessments that determine whether to perform additional assessments, these assumptions should no longer be used for refined risk assessments that will cause the regulated community to expend funds. This practice means that the Agency's risk assessments will always be overly conservative and trigger the need for additional, and unnecessarily stringent, standards more frequently than necessary.

The Agency, of course, recognizes this problem. The Agency noted,

> Such a scenario is very unlikely because individuals typically do not occupy the same residence for such a long period of time (*e.g.*, the median residential occupancy period is approximately 9 years, and less than 0.1 percent of the population is estimated to occupy the same residence for greater than 70 years). Because EPA typically assumes that an individual's excess lifetime risk of cancer is directly proportional to their duration of exposure to the carcinogen(s) in question, reducing the duration of exposure for individuals in the modeled population would reduce the estimates of their risk. To illustrate this, we performed an additional analysis that showed that the average excess lifetime cancer risks for individuals in the modeled population are likely to be about six times less than we predicted. These results are based on using the national average residency time of 12 years as the exposure duration rather than 70 years.

69 Fed. Reg. at 48347. Consequently, EPA performed an additional analysis using these more realistic assumptions and found that its assumptions regarding residential longevity overestimated risk by about 6 times. *Id.*

While it might not make a difference in this rule because an overestimate of 6 times will not lower the risk level to less than $1 \times 10^{-6}$, EPA should save itself the trouble of conducting additional analyses of its own risk assessment and instead adopt more realistic assumptions in the first instance.

Coalition for Responsible Waste Incineration

### C. EPA Should Evaluate The Risk From Only The Source Category.

The Agency has decided that its residual risk program should be based on risks from the entire industrial facility, rather than the risk remaining from the units within the source category being evaluated. 69 Fed. Reg. at 48340, fn. 5. The Agency decided to defer a total facility risk determination, however, until they make residual risk determinations for other parts of the facility. *Id.* at 48340 – 41. While CRWI understands the merits of this approach and acknowledges that it was discussed in the legislative debate, the statute clearly indicates that the risk determination must be based on emissions from the *source category* and not the emissions that come from the entire facility. The statute states:

> *If standards* promulgated pursuant to subsection (d) of this section and *applicable to a category or subcategory* of sources emitting a pollutant (or pollutants) *do not reduce lifetime excess cancer risks* * * * to less than one in one million, the Administrator shall * * * promulgate standards under this section for such source *category*.

CAA § 112(f)(2). (Emphasis supplied.)

EPA's position, which calls for further review of the risk when future residual risk rules are conducted, does not square with the language of the statute, imparts a lot of uncertainty to the program and would be unworkable. Facilities would be left to guess whether later rules might cause them to once again change their emissions control practices. And, because companies could have multiple source categories at their facilities in any combination, the Agency would constantly be performing multiple risk assessments for each rule. It will not be easy as EPA seems to believe in this rule, *i.e.*, when they complete the residual risk rule for the other emission points at coke ovens, the Agency will do another risk assessment for the total facility. Many industrial facilities are more complicated than that having units regulated by multiple MACT rules. Each time EPA performs a residual risk determination, it will need to examine whether this rule completes the residual risk regulation for any particular facility. If so, then it will need to perform an additional risk assessment. This is simply unworkable.

In addition, when EPA promulgated the Benzene NESHAP, they only considered the co-location of sources *within* the source category. 54 Fed. Reg. at 38050 – 51 (stating that the Agency only looked at co-location of the "model plants" that were the subject of the rule.) The Agency did not consider the risk posed by emissions from other sources.

CRWI submits that the statement of one Senator cannot overcome either the statutory language or the Congressional directive to follow the Benzene NESHAP


rule, particularly when this same Senator, in this same statement, expressly noted that his remarks were not providing EPA specific new direction. He stated,

> Mr. President, one of the most difficult issues for the Senate when this bill was on the floor last winter was the question of residual risk, that is how do we assure the public health and the environment will be protected in the event that the technology standards do not provide sufficient control? This was really a debate about cancer policy and how much cancer risk is acceptable from environmental pollution.
>
> The bill doesn't have the answer. To be sure, it includes a mechanism. It can be carried out. There will be a second tier of standards if they are necessary to protect public health. But it doesn't reflect a congressional statement of policy. Rather the bill defers to decisions made by the courts and by the Environmental Protection Agency. We simply return to current law in the second phase and ask EPA to set standards which provide an ample margin of safety to protect public health. That is the current law standard.

Legislative History, Vol. 1 at 875-876.

Consequently, consistent with Senator Durenberger's latter statement pointing to the Benzene NESHAP rule, EPA should only consider co-location of facilities when those sources are part of the source category being considered for regulation.

### D. EPA Should Not Require Further Reductions Unless Those Reductions Will Produce Discernible Results.

After determining the "acceptable level" of risk from these coke ovens, EPA proceeds to decide that further emission reductions will provide an ample margin of safety. EPA justifies this additional reduction based on costs, yet notes that the reduction in cancer risk will be so small that it is "well within the noise level of our ability to estimate." 69 Fed. Reg. 48350.

CRWI does not believe it is good policy to require additional reductions if the Agency cannot be sure that they will result in any benefit — no matter how inexpensive those reductions are. Instead, when performing an AMOS determination, EPA should first determine whether there are discernible effects from any further regulation before it decides to examine the cost of achieving that benefit.

This is particularly important since EPA has not yet stated that the 1 x $10^{-6}$ level contained in the statute is a limit on their regulatory authority for controlling carcinogens. Thus, as EPA has proposed in this rule, if more reductions can be performed cheaply enough (in the Agency's opinion), then EPA might require facilities to apply additional control practices that reduce risks below the 1 x $10^{-6}$ level. This too would be inconsistent with the statute.

### E. A Hazard Index Of 1.0 Should Not Equate To What Constitutes An Acceptable Level of Risk; Instead, It Should Be The Most Stringent Expression of What Constitutes An Ample Margin Of Safety.

Finally, EPA takes the position that a Hazard Index of 1.0 "ordinarily" represents the "acceptable level" for non-carcinogens. *See* Risk Assessment for Coke Oven MACT Residual Risk", December 22, 2003, OAR-2003-0051-0002, at 10. This means that the AMOS level could be lower. This is not appropriate. The RfC values which form the basis for calculating the Hazard Quotients and Hazard Index already contain sufficient layers of safety to represent AMOS. Because these multiple layers of conservatism are applied to the toxicological values used to calculate the Hazard Index, an H.I. of 1.0 should not be representative of the "acceptable level." Instead, it should be the most stringent AMOS level the Agency would adopt.

#### 1. The Ample Margin of Safety Level Accounts for Uncertainty in the Underlying Science

As the Agency knows, the D.C. Circuit Court of Appeals set forth its interpretation of the "ample margin of safety" provision in the Vinyl Chloride case. *NRDC v. EPA*, 824 F.2d 1146 (D.C. Cir. 1987). The court stated:

> The statute nowhere defines "ample margin of safety." The Senate Report, however, in discussing a similar requirement in the context of setting ambient air standards under section 109 of the Act, explained the purpose of the "margin of safety" standard as one of affording "a *reasonable* degree of protection . . . against hazards which research has not yet identified." S. Rep. No. 1196, 91st Cong., 2d Sess. 10 (1970) (emphasis added). This view comports with the historical use of the term in engineering as "*a safety factor . . . meant to compensate for uncertainties and variabilities.*" [Emphasis added] *See* Hall, *The Control of Toxic Pollutants Under the Federal Water Pollution Control Act Amendments of 1972, 63 Iowa L. Rev. 609, 629 (1978).*

*Id.* at 1152. The court continued,

> Congress, however, recognized in section 112 that the determination of what is "safe" will always be marked by scientific uncertainty and thus exhorted the Administrator to set emission standards that will provide an "ample margin" of safety...In determining what is an "ample margin" the Administrator may, and perhaps must, take into account the inherent limitation of risk assessment and the limited scientific knowledge of the effects of exposure....

*Id.* at 1165. Thus, the court specifically noted that the AMOS determination should consider "the limited scientific knowledge of the effects of exposure."

**2. RfCs and RfDs Already Account For Uncertainty in the Underlying Science and Therefore Represent the More Stringent AMOS Levels Rather Than "Acceptable Levels."**

As EPA knows, reference concentrations (RfC) that make up a hazard quotient or index are derived by first starting with the "no observable effects level" and then applying safety factors to arrive at the RfC. As the Risk Commission described in its report,

> RfC's "are considered to be exposure concentrations that are unlikely to be associated with adverse health effects. An RfC is derived by dividing a NOAEL, LOAEL, or BMD by "safety," "modifying," or "uncertainty" factors. In general a factor of 10 is used to account for uncertainty related to interspecies variability, and subchronic to chronic biosassay variability, respectively unless data (or expert judgment) exist to show that different factors should be used. If uncertainties have been resolved, such as for fluoride, a factor of 1 is used. Another factor of 10 is used if a NOAEL is unavailable. Every chemical has an RfC that is inversely related to its toxic potency. To obtain a hazard index, the ratios of exposure to RfC for each individual pollutant are combined.

Risk Assessment and Risk Management In Regulatory Decision-Making, Vol. 2, p. 110, fn. 1 ("Risk Commission Report"). Consequently, an RfC and its concomitant hazard quotient already use safety factors to account for scientific uncertainty. Thus, they are sufficient for representing what constitutes an ample margin of safety. Reference doses (RfD) are developed in the same manner.

For example, in the coke oven rule, EPA's IRIS database contains toxicological values for the following threshold pollutants. When establishing the RfC or RfD

levels for them, EPA applied safety factors to account for the uncertainty surrounding the health values in studies.

| Compound | Metric | Uncertainty Factor |
|---|---|---|
| Anthracene | RfD | 3000 |
| Benzene | RfD | 300 |
| Benzene | RfC | 300 |
| Cadmium | RfD | 10 |
| Fluoranthene | RfD | 3000 |
| Fluorene | RfD | 3000 |
| Toluene | RfD | 1000 |
| Toluene | RfC | 300 |
| Xylene | RfD | 1000 |
| Xylene | RfC | 300 |

The larger the uncertainty factor, the more conservative the RfC or RfD. Thus, EPA has already considered the scientific uncertainties associated with the NOEAL values and incorporated them into the RfC or RfD.

Congress knew this as well. In discussing the regulatory level for non-threshold pollutants Congress envisioned that the RfC or RfD could be equated to AMOS:

> The Administrator is also to promulgate a second round of standards for hazardous air pollutants other than carcinogens where MACT standards do not reduce emissions to a level below the "safe" threshold (the "no observable effects level" with an ample margin of safety), if a threshold can be identified for the pollutant and health effect.

S. Rep. No. 228, 101st Cong. Sess. at 149 (1990). Thus, in Congress' eyes, determining an AMOS level starts with the NOEL and ends at the RfC or RfD which they consider "safe." That, of course, is the process the Agency uses to derive the RfCs and RfDs. However, because the Agency has discretion to consider costs and other factors along with scientific uncertainties, CRWI believes that the AMOS level can be higher than the RfC or the RfD. The RfC or the RfD represents the most stringent AMOS level the Agency should adopt.

## IV. Conclusion

CRWI appreciates the opportunity to submit comments on this important, groundbreaking rule. In brief, we support


1. EPA adopting the two-step approach for setting standards it enunciated in the Benzene NESHAP rule.

2. EPA interpreting the statute as establishing a one in a million risk standard for triggering rulemaking, but not automatically representing the ample margin of safety level. Instead, EPA states that this is a goal to be assessed considering costs and other factors.

3. EPA using population risk estimates to se the standards.

4. EPA using a "target organ" approach when considering non-cancer risks.

5. EPA deciding that they are not required to redo the MACT floor when conducting 8-year MACT reviews under Section 112(d)(6).

CRWI also has a number of concerns about the Agency's proposal.

- EPA performed its risk assessment using the emission rate allowed by the technology-based standards, rather than the rates actually being emitted. EPA adopted this approach based on statutory language that could be interpreted differently. EPA notes that its approach "overstates actual emission levels" (69 Fed. Reg. at 48346 - 47), because it is rare that a facility will release maximum allowable emissions all the time. 69 Fed. Reg. at 48347.

- EPA based its risk assessment on some unrealistic assumptions including the assumption that individuals will be exposed to the highest allowable emissions 24 hours a day for 70 years. This means that the Agency's risk assessment will always be overly conservative and trigger the need for additional, and unnecessarily stringent, standards more frequently than necessary.

- EPA indicates that it will consider the risks from all sources when assessing risks rather than risks from just the source category. And, while the Agency decided to defer a total facility risk determination until they make residual risk determinations for other parts of the facility, this approach contradicts the plain words of the statute.

- EPA proposed that coke ovens make further emission reductions to ensure an "ample margin of safety" even though the actions they are requiring may not produce measurable results. CRWI submits that it is

not good policy to require additional reductions if the Agency cannot be sure that they will result in any benefit — regardless of how cost-effective or inexpensive. EPA should first determine whether there are measurable effects from any further regulation before it decides to examine the cost of achieving that benefit.

- EPA does not state that the $1 \times 10^{-6}$ level is a limit on their regulatory authority for controlling carcinogens and finally,

- EPA should not use a Hazard Index of 1.0 as representing the "acceptable level" for non-carcinogens. Instead, a Hazard Index of 1.0 should be the outer limit of what constitutes an ample margin of safety.