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Air and Radiation Docket and Information Center
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U.S. Environmental Protection Agency
401 M Street SW, Room M-1500
Washington, DC 20460

Docket No. A-99-30 (Corrected)

On behalf of the Northeast States for Coordinated Air Use Management (NESCAUM), thank you for the opportunity to comment on the proposed NESHAP for the Brick and Structural Clay Products Manufacturing and the NESHAP for Clay Ceramics Manufacturing. The following comments focus specifically on EPA's proposal to include risk-based exemptions in the rule. For the last 35 years, NESCAUM has been providing scientific, technical and policy support to our member states on air pollution issues of regional interest. The member states include the New England states, New York and New Jersey. The Northeast states have implemented risk-based air toxic control programs for over 20 years.[1] As a result, the NESCAUM Air Quality and Public Health Committee (AQPH Committee) possess both extensive public health risk assessment expertise and practical experience in the implementation of risk-based air toxic programs.

Since the 1990 Amendments were enacted the AQPH Committee has worked closely with EPA in the development of MACT standards and associated regulations that established a national program to regulate air toxic emissions from stationary sources. Overall NESCAUM believes that the MACT standard program has succeeded in implementing the Clean Air Act mandate that directs EPA to promulgate technology-based MACT standards first and then revisit those standards several years later to determine if high risks still remain in the vicinity of MACT-affected sources. We believe that this approach establishes a level-playing field of air pollution control across the U.S. However, as discussed in the following comments, **the inclusion of case-by-case risk-**

[1] EPA tracked the progress of state air toxic programs prior to 1990 in the National Air Toxics Clearinghouse (NATICH), which provided a detailed description of state air toxic programs throughout the 1980's. More recently, a comprehensive summary of state and local air toxic program activities was provided to EPA in the Appendices to the Recommended Framework for State/Local/Tribal Air Toxic Risk Reduction Program, Final Workgroup Report, September 2000.

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based exemptions into the first phase of the MACT program will negate the legislative mandate and jeopardize the effectiveness of the national air toxics program to adequately protect public health and the environment. Therefore, NESCAUM strongly recommends that EPA remove risk-based exemptions from the MACT standard process.

Introduction:

The Northeast states strongly endorse the comments submitted by the STAPPA/ALAPCO Air Toxics Committee on this proposal. In addition to STAPPA/ALAPCO comments, NESCAUM submitted written comments as an addendum to the transcript of the public hearing held on August 21, 2002 in North Carolina. Additional comments on inconsistencies of EPA's approach and programmatic concerns with this proposal are provided below. It should also be noted that the absence of comments on specific issues that EPA requested comments on in the Federal Register should not be construed in any way as support for this proposal. NESCAUM finds the inclusion of risk-based exemptions fundamentally flawed in its entirety.

NESCAUM believes that any logical and reasonable interpretation of the plain language of Section 112(b)(4) of the Clean Air Act (CAA) and the regulatory precedent established in over 80 MACT standards would reject the inclusion of risk in the first phase of the MACT standard process. As you are aware, the Northeast states have been implementing risk-based air toxic control programs for over 20 years. Since 1990, the implementation of state and federal air toxic requirements in Title V permits has required that the legal and regulatory features of each MACT standard undergo an extraordinary level of scrutiny by the legal, permitting and public health divisions of each state air quality agency. In the 12 years that the Northeast states have collaborated with OAQPS staff on the development of MACT standards for the national air toxics program there has been no indication or discussion of any kind regarding the notion of risk-based exemptions in the first phase of the MACT program. These activities include: numerous stakeholder workgroups on specific regulations (e.g. Urban Air Toxics Strategy, Residual Risk Strategy), annual meetings hosted by OAQPS that are dedicated to updating state and local agencies on Title III regulations, STAPPA/ALAPCO monthly calls with a designated time slot for EPA to provide updates on air toxics regulations, STAPPA/ALAPCO Directors meeting attended by OAQPS management, and various overviews and presentations[2] made available to state and local agencies through the STAPPA/ALAPCO Secretariat and NESCAUM. In fact, we are aware of only one process (i.e., Residual Risk stakeholder workgroup), established in November 2000, in which OAQPS has committed to work with state and local agencies on the development of risk assessment and risk management strategies for MACT-affected source categories.

It is, therefore, unprecedented and alarming that EPA is proposing such a radical change at the end of Phase 1 of the MACT standard process by including risk-based

[2] For example, presentations by Sally Shaver on the national air toxics program are provided to states and local agencies via the STAPPA/ALAPCO website.

exemptions. We are deeply concerned that EPA directly references in the proposal a fundamentally flawed interpretation of the CAA and Section 112(d)(4) that was written by an industry, which is currently subject to regulation by EPA (American Forest and Paper Industry (AF&PA). Of particular concern is the unprecedented proposal by AF&PA to insert "de minimis exemptions" and "cost" into the MACT standard process. To our dismay, these actions have the appearance of selected regulatory relief for a small number of sources. However, even more troubling, is the fact that EPA's proposal lacks any resemblance to EPA's science policies, guidelines, and practices related to risk assessment and risk management at the Agency. As such, EPA's proposal for risk-based exemptions effectively misinterprets not only the CAA but also the guidelines and science policies established by EPA to ensure adequate protection of the public health and the environment.

Inconsistencies with EPA's Risk Assessment Guidelines:

The current proposal does not adhere to the Agency's established guidelines for characterizing the human health and ecological risks associated with exposure to environmental pollutants.[3] These guidelines provide a framework for summarizing the four steps identified by the Agency as necessary to conduct risk assessments (i.e., hazard identification, exposure assessment, dose-response assessment, and risk characterization). EPA's science policy for risk assessment and risk characterization dictates that the assessments be conducting according to Agency guidelines, that the core assumptions and science policies are consistent and comparable across programs, and that they are well-grounded in science (EPA memorandum, March 21, 1995).

There are a number of principles that form the basis for an EPA risk assessment and characterization, which are not mentioned or referenced, in the current proposal. For example:

- the requirement that risk assessments should be transparent, in that the conclusions drawn from the science are identified separately from policy judgements, and the use of default values or methods and the use of assumptions in the risk assessment are clearly articulated.

- the requirement that risk characterizations should include a summary of the key issues and conclusions of each of the other components of the risk assessment, as well as describe the likelihood of harm. The summary should include a description of the overall strengths and the limitations (including uncertainties) of the assessment and conclusions.

In addition, the proposal does not incorporate risk assessment guidelines for conducting multi-pathway risk assessments – which is critical because the major pathway of exposure to toxic metals emitted by this sector is the ingestion pathway. The proposal

[3] EPA Risk Characterization Program, March 21, 1995; see National Center for Exposure Assessment website for guidelines (www.epa.gov/ncea)

also does not reference Agency guidelines for cumulative risk assessment that specifically require the consideration of non-inhalation pathways of exposure in human health risk assessments.[4] EPA appears unaware of these guidelines since it requests comment on whether or not non-inhalation routes should be included. In summary, EPA proposes a disorganized and cursory approach to implement risk-based exemptions, which falls far below the quality of risk analysis typically required by EPA across other Agency programs.

One of the serious problems with this flawed approach is that it could have impacts on other EPA programs. For example, the goals of EPA's March 1995 Risk Characterization Policy of transparency, clarity, consistency and reasonableness in Agency risk assessments expressly applies to risk assessment practices across the Agency. The inconsistencies between EPA's proposal to provide risk-based exemptions in the MACT standard process and risk assessment guidelines undermine these regulatory programs throughout the Agency. These include but are not limited to the following programs: primary and secondary National Ambient Air Quality Standards, Acid Rain Program, Stratospheric Ozone Program, Radionuclide Program, Indoor Air Program, TSCA's Existing RM1 and RM2 Chemical Assessment Program, New Chemicals Program, National Lead Abatement Program, Toxic Release Inventory Petitions, FIFRA (Reregistration and Special Reviews), Hazardous Waste Identification and Listing, Site-specific risk assessments for RCRA waste combustion facilities, RCRA Corrective Action, Superfund, Standards for the Use of Disposal of Sewage Sludge, Ambient Water Quality Criteria for Protection of Human Health, MCLs for Drinking Water, and the Relative Source Contribution Policy.

Specific Comments on Applicability Cutoff Proposal:

EPA's proposal to apply applicability cutoff's based on the contention that each of the pollutants emitted from the source are threshold pollutants and that the emissions will not exceed threshold levels, with an ample margin of safety, is baseless. Of the ten metals EPA is regulating under this proposal, eight are known or probable human carcinogens (i.e., arsenic and hexavalent chromium are known human carcinogens, and cadmium, beryllium, nickel compounds, lead, and selenium are probable human carcinogens.) Evidence for known or probable carcinogenicity of these metals is well documented by EPA in the current proposal, on U.S. EPA's Integrated Risk Information System (IRIS), and by International Agency for Research on Cancer (IARC) in monographs published in 1987 and 1994.[5]

With respect to consideration of carcinogens with thresholds or nonlinear modes of action, EPA again fails to thoroughly consider in the proposal that the Draft Cancer

[4] Cumulative Risk Assessment Guidance- Phase I Planning and Scoping, July 3, 1997.
[5] IARC: Monographs on the Evaluation of Carcinogenicity: An Update of IARC Monographs. Lyons: World Health Organization, International Agency for Research on Cancer, 1987. Vol. 1-42. Suppl 7.; and IARC: Monographs on the Evaluation of Carcinogenicity: Monographs on the Evaluation of Risks to Humans: Cadmium, Mercury, Beryllium, and the Glass Industry. Lyons: World Health Organization, International Agency for Research on Cancer, 1994. Vol. 58

Risk Guidelines specify factors[6] to support the selection of a nonlinear (margin of exposure) approach to dose-response assessment. If EPA considered these factors it would become evident that they do not apply to the HAPs emitted from the brick/structural clay/ceramic clay source category. These factors were established to address the issues concerning the use of epidemiologic studies to estimate population risks at low levels of exposure. EPA guidelines specify that the apparent nonlinearity at low exposure doses in the studies must be supported by empirical evidence, including biological reasons for rejecting linearity. If the data are weak, then linearity must be assumed. For example, one of the HAPs regulated in this proposal is arsenic, which has a relatively robust database on cancer incidence in human populations compared to other HAPs. Yet, the Science Advisory Board concluded that "Information on the mode of action of arsenic and other available data that can help to determine the shape of the dose-response curve in the range of extrapolation are *inconclusive* and do not meet EPA's 1996 state criteria for departure from the default assumption of linearity."[7] The fact that several HAPs emitted from this source category are not now and never will be considered "threshold" pollutants demonstrates the flaws in EPA's proposal to consider applicability cutoffs to implement risk-based exemptions.[8]

As a final point, the current proposal lacks a fundamental understanding that metals emitted from this sector are ubiquitous and persistent in the environment and that exposure is rarely to individual pollutants but a complex mixture. Adherence to EPA's risk assessment guidelines would have uncovered this flaw. For example, the dose-response assessment would evaluate the role of metals as promoters or co-carcinogens with organic carcinogens, which must be considered and addressed in evaluating risks to human health. In addition, several factors that influence the toxicity of metals would be considered.[9] These include the interactions with essential metals, formation of metal-protein complexes, age and stage of development of the exposed population, lifestyle factors, chemical form or speciation and immune status of the host. The proposal also ignores the cumulative risks that result from exposure to metals and highly irritating gases (i.e., HF and HCl). Although each by itself may pose a risk below a designated threshold, the accumulation of these pollutants and simultaneous exposure to the complex mixture is a critical component of the risks associated with emissions from this sector but not addressed in the proposal. This is particularly important to include in the risk

[6] A tumor mode of action supporting nonlinearity applies (e.g. some cytotoxic and hormonal agents such as disruptors of hormone homeostasis) and the chemical does not demonstrate mutagenic effects consistent with linearity. A mode of action supporting nonlinearity has been demonstrated and the chemical has some indication of mutagenic activity but it is judged not to play a significant role in tumor causation. (Draft Cancer Risk Guidelines 7/02/99).

[7] "Arsenic in Drinking Water" by the Subcommittee on Arsenic in Drinking Water, Committee on Toxicology, Board on Environmental Studies and Toxicology, Commission on Life Sciences, National Research Council, National Academy Press, Washington, DC. 1999.

[8] With respect to the other exemption option, NESCAUM is convinced that subcategorization is impossible within the statutory constraints of the CAA.

[9] Goyer, Robert A. Toxic Effects of Metals in Casarett and Doull's Toxicology: The Basic Science of Poison, Fifth Edition, McGraw Hill Publishers.

assessment because gas-particle phase interactions may enhance the toxicity of the mixture, especially in sensitive subpopulations, including asthmatics.[10]

Programmatic Concerns:

Although the proposal is introduced under the heading "How can we reduce the cost of the proposed rule[11]?" it only considers the cost to the regulated source category. The proposal does not take into account the costs and resources that are required to implement risk-based exemptions in the current MACT standard program. We reiterate that our extensive experience in implementing risk-based air toxic control programs provides the Northeast states with a unique understanding of the legal, technical and financial aspects of implementing risk-based programs. For these reasons, it is quite evident that EPA has not considered the substantial costs and resources to state and local agencies that are necessary to implement risk-based exemptions in the current MACT program. For example, EPA does not consider the costs and resources associated with:

(1) the public process required in reviewing and approving the proposed approaches and, if approved, making the substantial changes to existing regulations;
(2) the development of methods and guidance for human health and ecological risk assessments of affected sources;
(3) the review by state agencies of the assessments and assurance of adequate public participation in the process. This is particularly critical considering the current budget constraints in state agencies throughout the country; and
(4) the collection and verification of source-specific data needed for conducting human health and ecological risk assessments.

Finally, risk-based exemptions are such an implausible interpretation of the CAA that states do not even have the authority to grant them under their respective Title V permit programs. As such, NESCAUM is not aware of any practicable and verifiable method to ensure source emissions remain below a specified emission level since MACT standard applicability is the gate-keeper for being subject to the federal air toxic regulations, including but not limited to a Title V operating permit. Once the source is exempt from the MACT standard – which is the intent of this proposal – the source would not be subject to monitoring, reporting, and record-keeping requirements that are needed to demonstrate compliance. It should also be noted that the current proposal does not consider the costs and resources that are required to implement an entire new layer of compliance on sources that are exempt from MACT standards and, therefore, not covered under the Title V operating permitting program.

[10] Ibid. Costa, D and Mary Amdur. Air Pollution, Chapter 28.
[11] We also note again that it is illegal for "cost" to be considered at the stage of the MACT standard process.

In summary, it is noteworthy that the Inspector General of the EPA recently found that EPA is nearly two years behind in fulfilling its statutory responsibilities for implementing all Phase 1 air toxic standards (also known as MACT standards) and that the delay has the potential for serious harm to the public and the environment. The inclusion of risk-based exemptions in 10-year MACT standards will only further delay this process. This delay in reducing air toxic emissions has a direct impact on the public health of millions of Americans. We strongly urge EPA to reject the inclusion of risk-based exemptions in the brick/structural clay/ceramic clay MACT standard and expeditiously propose and promulgate the remaining technology-based MACT standards without such exemptions.

Again, thank you for your consideration of our comments. Please call me if you have any questions.

Sincerely,

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