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Connecticut Bureau of Air Management, Anne Gobin, Acting
Maine Bureau of Air Quality Control, James Brooks
Massachusetts Bureau of Waste Prevention, Barbara Kwetz
New Hampshire Air Resources Division, Robert Scott
New Jersey Division of Air Quality, William O'Sullivan
New York Division of Air Resources, David Shaw
Rhode Island Office of Air Resources, Stephen Majkut
Vermont Air Pollution Control Division, Richard Valentinetti

July 2, 2004

EPA Docket Center (Air Docket)
Attn: Docket No. OAR -2003-0189
U. S. EPA West
Room B108 (Mail Code 6102T)
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Re: Proposed National Emission Standards for Hazardous Air Pollutants (NESHAP) for Stationary Combustion Turbines, which were published in the *Federal Register* on April 7, 2004 (69 *Federal Register* 18327).

Dear Sir or Madam

The Air Quality and Public Health Committee appreciates the opportunity to comment on the delisting of four subcategories of combustion turbines under section 112(c)(9) of the Clean Air Act. We concur with the comments against this proposal from the New York Department of Environmental Conservation and the STAPPA/ALAPCO Air Toxics Committee. We are profoundly concerned that the EPA is proposing to delist combustion turbines based on the CIIT cancer potency factor for formaldehyde, which is substantially less health protective than the current IRIS value. EPA's decision to use the CIIT value for assessing cancer risks associated with formaldehyde exposure was clearly premature given the findings of new epidemiologic studies, which, according to EPA's Office of Research and Standards (ORD), supports the current IRIS risk value.[i] It is also disturbing that OAR/OAQPS proceeded with the use of the CIIT value while (1) ORD was finalizing the toxicological review of formaldehyde for IRIS, which included analysis of the new epidemiologic studies, and (2) the International Agency for Cancer Research (IARC) was conducting an international scientific meeting in June 2004 to also analyze the new epidemiologic studies on formaldehyde.

The potentially serious problems associated with EPA's decision to use the CIIT value in this proposal and other related regulations are now exacerbated by the June 2004 finding by IARC that the new information from these epidemiologic studies increases the overall weight of evidence that "formaldehyde **is** carcinogenic to humans.[ii] Specifically, IARC stated: "Previous evaluations, based on the smaller number of studies available at that time, had concluded that formaldehyde was *probably carcinogenic to humans*, but new information from studies of persons exposed to formaldehyde has increased the

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overall weight of the evidence**."**

We believe that these new human studies on formaldehyde and other relevant information, including the CIIT assessment, need to be evaluated by EPA according to Agency policies and procedures associated with scientific analysis and development of draft IRIS values. The IRIS procedures also contain an internal and external peer review and public review process, which are required in the development of IRIS values. These review procedures were not followed in the decision to use the CIIT value in OAR/OAPQS proposals and final regulations. We believe that it is critical for EPA to follow their own procedures and policies to ensure the development of scientifically defensible dose-response values.

Therefore, we strongly urge EPA to err on the side of protective public health policy and withdraw the proposal to delist combustion turbine subcategories based on the CIIT value. We also urge EPA to withdraw the use of the CIIT value from all risk assessments of formaldehyde exposure conducted by OAQPS, including the risk-based exemptions in the plywood/composite wood and ICI boiler NESHAPs, and the National Scale Assessment.

Specific Comments

EPA concluded in the Federal Register notice (69 *Federal Register* 18327) and in the Combustion Turbine Source Category Risk Characterization report (March 25, 2004) that the risk estimates used to support the delisting of the gas turbines are health-protective and based on "conservative worst-case assumptions." However, we believe that this is not the case for the following reasons:

1. EPA used only annual averages to evaluate chronic effects from exposure to combustion turbine emissions and did not assess risks associated with acute effects or short-term peak exposures to certain HAPs emitted from stationary turbines, such as the aldehydes. EPA cites these health effects qualitatively in the March 25, 2004 report but does not quantify the risks associated with them. For example, an excerpt from EPA's risk assessment is provided below:

   "Acute (short term) inhalation exposure to formaldehyde has caused bronchitis, pulmonary edema, pneumonitis, pneumonia, and death due to respiratory failure at high concentrations. Chronic (long-term) exposure can cause dermatitis and sensitization of the skin and respiratory tract. Other HAPs emitted in significant quantities from stationary combustion turbines include toluene, benzene, and acetaldehyde. The health effect of primary concern for toluene is dysfunction of the central nervous system (CNS). Toluene vapor also causes narcosis. Controlled exposure of human subjects produced mild fatigue, weakness, confusion, lacrimation, and paresthesia; at higher exposure levels there were also euphoria, headache, dizziness, dilated pupils, and nausea. After-effects included nervousness, muscular fatigue, and insomnia persisting for several days. Acute exposure may cause irritation of the eyes, respiratory tract, and skin. It may also

cause fatigue, weakness, confusion, headache, and drowsiness."

Therefore, without quantitatively evaluating the acute, short-term effects from exposure to HAPs from combustion turbines, the risk estimates for non-cancer effects may be underestimated.

2. EPA assesses risks based on exposure to HAPs emitted only from the combustion turbines and does not take into account other sources of exposure to these HAPs that occurs in the vicinity of the turbine. As a result, human health risks are underestimated in the EPA risk assessment.

3. As discussed above, EPA inappropriately used a cancer potency factor for formaldehyde that may substantially underestimate cancer risks.

   The change in the formaldehyde concentration between the IRIS and CIIT values is significant – the value associated with an excess cancer risk of one-in-one million goes from 0.07 $\mu g/m^3$ (based on the IRIS value) to 180 $\mu g/m^3$ based on the CIIT value. Considering such a significant increase in potential exposure and associated cancer risks from this decision, EPA should have considered the new information presented in the epidemiologic studies on formaldehyde that were published in 2003, or waited for ORDs assessment that is expected this summer, before deciding to adopt the CIIT value that is four orders of magnitude lower than the IRIS value [J Natl Cancer Inst 2003;95: 1615–23 and J Natl Cancer Inst 2003;95:1608–15].

   Furthermore, EPA should have considered the uncertainties associated with the CIIT model. According to a review by Health Canada[iii] "*these uncertainties for which sensitivity analyses would have been appropriate include the use of individual rat, primate, and human nasal anatomies as representative of the general population, the use of a typical-path human lung structure to represent people with compromised lungs, the sizes of specific airways, the use of a symmetric Weibel model for the lung, the estimation of the location and extent of squamous and olfactory epithelium and of mucus- and non-mucus-coated nasal regions in the human, and the values of mass transfer and dispersion coefficients. The lack of human data on formaldehyde-related changes in the values of key parameters of the clonal growth component accounts for much of the uncertainty in the biologically motivated case-specific model*."

   Finally, we reiterate that while we recognize that there may be more recent, credible and relevant information available than is contained in IRIS, EPA also has an established internal, external and public review process for entities other than EPA to have new information considered for incorporation into IRIS. However, the current approach used by OAR/OAQPS short-circuits the IRIS program by replacing IRIS values without an internal review by ORD, and external peer review of the draft assessments. This has serious implications for a program that had widespread credibility in providing consistent Agency-wide peer reviewed dose-response values for the past two decades. It is also confusing

and inefficient for states and the public when EPA offices use different and potentially conflicting dose-response values. Therefore, EPA should establish procedures for an external review process that is transparent and well publicized before an EPA office decides to use a value that is different than the one in IRIS.

4. In regard to the important topic of sensitive subpopulations, EPA's risk assessment did not account for the sensitivities of children to environmental stressors, which further underestimates the cancer risks to exposed populations. For example, Dr. Gary Ginsberg of the Connecticut Department of Health[iv] found that for the vast majority of chemicals that have cancer potency estimates, the underlying database is deficient with respect to early-life exposures. This data gap has prevented the derivation of cancer potency factors that are relevant to early-life exposures, and so assessments – including EPA's risk assessment of combustion turbines – do not fully address children's risks. Dr. Ginsberg found that short-term exposures to these chemicals in early-life are likely to yield a greater tumor response than short-term exposures in adults, but similar tumor response when compared to long-term exposures in adults. To address children's sensitivities to carcinogens, Dr. Ginsberg recommends the following:

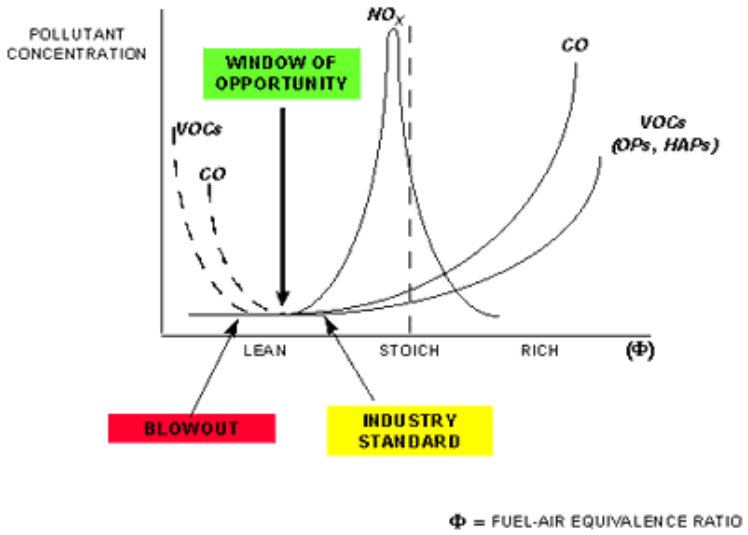
    - Do not prorate children's exposures over the entire life span or mix them with exposures that occur at other ages;
    - Apply the cancer slope factor from adult animal or human epidemiology studies to the children's exposure dose to calculate the cancer risk associated with the early-life period; and
    - Add the cancer risk for young children to that for older children/adults to yield a total lifetime cancer risk.

    Dr. Ginsberg's approach allows for the unique exposure and pharmacokinetic factors associated with young children to be fully weighted in the cancer risk assessment. This approach should be included in EPA's analyses, especially for such ubiquitous pollutants as formaldehyde.

    It should also be noted that in response to recommendations that OEHHA consider the CIIT model during the public review of the Draft Prioritization of Toxic Air Contaminants Under the Children's Environmental Health Protection Act (July, 2001) OEHHA made the following point: "OEHHA is familiar with the dose-response analyses described by the commenter,[v] but emphasizes that the results of these calculations have no direct bearing on the current process of prioritization under [the Act]. Indeed, it might be concluded that the emphasis on the clonal expansion model in the formaldehyde analysis provides a clear mechanistic and mathematical basis for expecting that there would be a greater sensitivity to the carcinogenic effect at younger ages."

5. It appears that neither the Gas Turbine Association (GTA) petition nor EPA's risk assessment took into account the potential increase in HAP emissions that may occur under various operating conditions, such as when combustion gas systems

shift to operating conditions that reduce NOx while maintaining high combustion efficiency. For example, the researchers at the Irvine Combustion Laboratory of the University of California found that HAP emissions may increase due to operation on the edge of stability, as shown below.[vi] In light of the substantial need to reduce ozone precursors (OP) in non-attainment areas – particularly NOx – we believe that unless a broad range of potential exposure scenarios are considered in the risk assessment for combustion turbines, including the potential increase in turbine emissions from certain operating conditions.



In summary, we do not believe that the delisting criteria set forth in Section 112(c) have been demonstrated by EPA in support of the delisting of stationary combustion turbines. In fact, given the information outlined above, we believe that the risk estimates in EPA's assessment of combustion turbines could be significantly underestimated. Therefore, EPA should withdraw its proposed decision to delist the four subcategories of stationary combustion turbines. EPA should also withdraw the use of the CIIT value from all risk assessments or related activities associated with formaldehyde exposure conducted by OAQPS, including the risk-based exemptions in the plywood/composite wood and ICI boiler NESHAPs, and the National Scale Assessment.

Thank you for consideration of these comments. Please contact David Wright, Chair of the Air Quality and Public Health Committee and Director of the Maine DEP Air Toxics Program (207-287-6104) or Margaret Round at NESCAUM, if you have any questions.

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[i] Based on discussion between the AQPH Committee and Dr. Peter Preuss, Director of NCEA of ORD, April 8, 2004.

[ii] The recent review of these studies by the International Agency for Research on Cancer has concluded that: "Twenty-six scientists from 10 countries evaluated the available evidence on the carcinogenicity of formaldehyde, a widely used chemical", reports Dr Peter Boyle, Director of the International Agency for Research on Cancer (IARC), part of the World Health Organization. The working group, convened by the

IARC Monographs Programme, concluded that formaldehyde is carcinogenic to humans. Previous evaluations, based on the smaller number of studies available at that time, had concluded that formaldehyde was probably carcinogenic to humans, but new information from studies of persons exposed to formaldehyde has increased the overall weight of the evidence.
Based on this new information, the expert working group has determined that there is now sufficient evidence that formaldehyde causes nasopharyngeal cancer in humans, a rare cancer in developed countries. "Their conclusion that there is adequate data available from humans for an increased risk of a relatively rare form of cancer (nasopharyngeal cancer), and a supporting mechanism, demonstrates the value and strengths of the Monographs Programme," emphasized Dr Boyle. The working group also found limited evidence for cancer of the nasal cavity and paranasal sinuses and "strong but not sufficient evidence" for leukaemia. The finding for leukaemia reflects the epidemiologists' finding of strong evidence in human studies coupled with an inability to identify a mechanism for induction of leukaemia, based on the data available at this time. "By signalling the degree of evidence for leukaemia and cancer of the nasal cavity and paranasal sinuses, the working group identified areas where further clarification through research is needed. This represents a service to Public Health", Dr Boyle concluded."

[iii] Journal of Toxicology and Environmental Health, Part B, 6:85–114, 2003

[iv] Risk Analysis Volume 23, Issue 1, Page 19; February 2003

[v] Comment by B. Landry of Venable, Attorneys at Law, for the Composite Panel Association ("CPA"), formerly the National Particleboard Association

[vi] http://www.apep.uci.edu/indexucicl.html.