Comments on Background Documents

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Hazard Identification

All associations reported in ecological epidemiology studies are presumed to be causal. **There is no process for considering the totality of the scientific evidence as per the IARC Cancer Hazard Review where the results of epidemiology, animal and human toxicology, and mechanistic evidence are considered together.** As a result, we now are acting under the regulatory assumption that everything that can be measured in ambient air causes acute and or chronic mortality (all sizes and chemistry of PM, ozone, SO_2, carbon monoxide, nitrogen dioxide), and that ecologic studies can accurately separate out the effects of the individual pollutants for purposes of impact/benefits assessments.

As an example, ambient levels of SO_2 are assumed to produce acute mortality, with no threshold. This assumption ignores the fact that: 1) the SO_2 E-R functions are severely confounded by PM; 2) toxicology and human clinical data do not support mortality at low levels; and 3) there is no biological mechanism to explain how SO_2, a simple water soluble upper respiratory tract irritant, alone, could produce acute mortality at ppb levels.

Risk Characterization

Worst-case exposure response (E-R) functions from positive studies are used to assess risks. The results of valid negative ecologic studies as well as results of human clinical, animal, and toxicology data are completely ignored in the risk characterisation phase (e.g., ASHMOG, VA studies on PM; ozone human clinical data).

The confounding effects of co-pollutants on E-R functions are ignored, resulting in double- and triple counting of health effects. For example, E-R functions for PM derived from models including SO_2 are used to assess PM mortality, then E-R functions for SO_2 mortality are used without adjustment for PM. Similarly, E-R functions for acute mortality are used without even considering confounding effects of $PM_{2.5}$. This begs the question, how many times can the same people die from air pollution?

All pollutants are assumed to produce severe health effects (e.g. acute or chronic mortality) with *no threshold,* even though the overall scientific data indicate otherwise. The no threshold assumption for all pollutant ignores the fact that ecological studies have limited statistical ability to assess thresholds. Further, recently reported empirical studies of ecologic data sets have have actually observed thresholds in both time series (Smith $PM_{2.5}$, Daniels PM_{10}, Nicolich TSP) and chronic (e.g., Abrahamowica, 2003 - ACS sulfate) data sets. Finally, he existing animal, human clinical, and mechanistic data, as well as the chemistry data on the criteria pollutants themselves, generally support the concept that there is or should be a threshold for health effects.

Risk Communication

There is an ongoing campaign to exaggerate the effects or air pollution and mislead the public on the health significance of existing levels of air pollution. This is evidenced by the fact that the public believes air pollution is getting worse when in fact the levels of most all criteria pollutants have decreased dramatically in North America and Europe over the last decade.

Air pollution risks are inappropriately compared to other risks resulting in a mis-allocation of public health resources. An example is directly comparing air pollution mortality and car accident mortality rates. Air pollution mortality is based on ecologic data, which have great uncertainty. Further, those dying are likely in the late stages of their lives. In contrast, car accident mortality is based on individual level data which have great certainty. Those dying in car accidents are on average much younger in age.

Reduction Strategies

Some of the key reduction strategies, such as further reducing sulfur in fuels, appear to be overly simplistic and not based on the latest science. In various places in the background documents, reducing sulfur in fuels and sulfate levels in ambient air is identified as a key reduction strategy. Presumably, this is based on the idea that reduced airbone sulfate levels would be expected to produce major public health benefits, for example, reduced chronic mortality. In fact, a recent publication indicates a threshold exists for sulfate PM mortality in the ACS study, at a level far exceeding current ambient sulfate levels (Abrahoamowicz, Tox Env Hlth 66, 2003). Further, recent toxicology reviews conclude that sulfate PM has little biological potency and is not likely to be the causative agent for mortality (Schlesinger, Inh Tox. 15, 2003). Therefore, it would appear that a PM reduction strategy based mostly on lowering sulfur in gasoline or other fuels would not be expected to produce significant public health benefits.

Dr. Hans-Guido Mücke

1. What is the European scale we are talking about? - Western Europe, European Union Member States (incl. or excl. accession countries) or the 52 Member States of the WHO European Region (for which I am serving within my work, including Eastern Europe, Causasus and Central Asia - EECCA) ? I am convinced that Canada and US is equally highly developed and give a homogenuous picture within the north American region, which makes comparsions easily possible. This is clearly not the case within whole Europe! The WHO European Region is as heterogenuous as the WHO Region of the Americas (from north to south). E.g. many EECCA countries have air pollution problems, Western Europe has solved meanwhile. And sometimes obvious air pollution problems within EECCA are not of highest priority, because much more elementary problems suffer the population, e.g. infections due to contaminated drinking water, poor job and living conditions, limited energy sources for heating and cooking,.But, if we are looking for clean air and health strategies and best options and policies for air quality management, NERAM and AIRNET should think and act globally for a sustainable environment and health - air pollution do not have any border. One good example is the UNECE convention on long-range transboundary air pollution, and could be the ratification of the Kyoto protocol, incl. US and Russia. I think, the European scale should be discussed - it is very important for harmonized clean air policy actions.

2. For an easier understanding, I wish NERAM could gives examples, how deep policy was really influenced by such voting procedures. It was written: 'This recording ....has been done succefully many times in the past by NERAM'. What was the success? What was/were the real policy input(s) from such votings? And how such success/input was measured?

3. With regard to point 2., the conference includs the NERAM/Airnet colloquium on Strategies for Clean Air and Health.

It is at least funny for me to read and not easy to understand that 'the statement identifying directions for science and policy to improve air quality and to protect public health will not represent the opinion of NERAM or Airnet' - why not?
I thought the Network for Environmnetal Risk Assessment and Management is independent enough from policy to give policy recommendations. But maybe I am wrong. Thank you very much for paying attention to my remarks.