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Catherine Witherspoon
Executive Officer
California Air Resources Board
P.O. Box 2815
Sacramento, CA 95812

Subject: Comments on Proposed Emissions Reduction Plan for Ports and Goods Movement in California, Release Date March 21, 2006

Dear Ms Witherspoon:

On behalf of the BNSF Railway Company (BNSF), we appreciate this opportunity to comment on the Emission Reduction Plan (ERP) for Ports and Goods Movement. At our Goods Movement Task Force meeting on March 30, 2006, the co-chairs requested, in light of the brief comment period before the California Air Resources Board's (CARB) hearing on April 20, 2006, that Task Force members submit comments as early as possible with respect to concerns they have with the proposed draft. To meet this objective we are submitting preliminary comments on the health risk assessment, its' results and their use in the draft benefits analysis. We acknowledge the considerable amount of effort put forth by the California Air Resources Board in generating the initial draft and subsequent revision. We appreciate the need for rapid progress in the development of the Goods Movement Plan and the attendant Emissions Reduction Plan, and we look forward to continuing to work closely with CARB on the Goods Movement Plan.

We are concerned that in the haste to do "something," an ERP that does not provide sufficient detail to support peer review and that includes some errors and unjustified assumptions has been produced. We are also particularly concerned that the methods used for risk assessment are based on a flawed application of attributable risk that, if unchanged, will provide misleading communication of risk and incorrect estimates of the benefits of emission controls. In addition, the ERP represents a second State-recommended approach to the evaluation of health effects from diesel (i.e., in addition to the current OEHHA/CARB approach for evaluating diesel using the REL exposure limits). We are concerned that having two approaches for evaluating the health effects of diesel emissions will create confusion regarding the selection of the appropriate approach for the various sources of diesel exhaust in the State. Having two distinct approaches for evaluating the health effects of diesel exhaust would create two classes of diesel emission

sources: those that are evaluated using the State's REL and those that are evaluated using the States concentration-response function for PM2.5 from diesel emissions. The ERP also appears to create a second approach outside of the State Implementation Plan for regulating diesel-derived PM2.5.

Our primary technical and policy concerns are summarized below:

The Concentration Response Functions Used in the Risk Assessment Do Not Provide a Valid Basis for Estimating Health Effects

The first chapter of the report addresses public health impacts, and our primary concern with the report is that there is a fundamental flaw in the approach being taken to use the epidemiology studies cited in the report to quantify health risks and to estimate the benefits of proposed control measures. We note that an attributable risk or attributable fraction approach is used to incorporate epidemiological study results into the risk assessment presented in the Emission Reduction Plan for Goods Movement. The conversion of relative risk estimates into attributable fractions is assumption-laden and subject to significant limitations and, consequently, is inaccurate and scientifically indefensible.

Conceptually, an attributable fraction is simply the proportion of disease occurring in a population that is associated with a specific risk factor. It does not assure that the factor is causally associated and, therefore, does not necessarily predict what might occur in the absence of the factor. Further, each risk factor that is associated with the occurrence of disease will have an attributable fraction greater than zero. It is important to consider that the sum of all attributable fractions is unlimited; and, thus, the interpretation of any **specific** attributable fraction requires several caveats and may not be possible.

- For example: If the attributable fraction for a given disease is 80% for cause X, 20% for occupational exposure, 10% for family history, 50% for cause Y, and 15% for cause Z, 175% of the disease will have been "attributed" to these selected causes.

It is clear that the interpretation of any specific attributable fraction (such as that of PM2.5) will, assuming that the factor is causal, overestimate the amount of disease that can be prevented by its reduction or elimination. In the CARB proposal, however, attributable risk measures are interpreted in the contra-positive, such as: "If the exposure had not occurred, then x (or x %) of all cases currently in the population could have been avoided." From the above example, it is clear that elimination of any **one** cause from the above example will not eliminate a comparable proportion of the disease.

Attributable risk calculations assume that the risk factor is a sufficient cause of the disease and that the cause is completely independent of all others. If competing risk factors are also associated with the primary exposure of interest, they may obscure or "confound" the exposure/outcome association of interest. For known confounders, statistical analyses can "adjust" for these effects – however, it is likely that residual confounding resulting from unknown/unmeasured confounders or confounders that can not be statistically separated remains. Further, the methodology, as proposed, ignores

any situation in which air pollutants interact with each other, violating a basic assumption of independence. With respect to diesel emissions, consideration of co-pollutants is essential to adequately adjust for confounding or interactions. To our knowledge, only a handful of co-pollutants have been investigated in the epidemiologic literature, and relationships among co-pollutants and health effects are neither well described nor understood. The lack of ability to attribute health effects observed in the CARB-sponsored Children's Health Study to particulates or other individual, closely-associated pollutants was clearly identified in the final report issued by CARB (2004) on the study, for example.

In the current emission reduction plan, results from Pope et al. 2002 are used to infer the response rate for PM2.5 and premature death. While the results from Pope were adjusted for 44 individual level covariates, there was no attempt to control for confounding associated with co-pollutants. The current draft indicates that results from Jerrett et al. (2005) are being considered as an alternative to the response rates from Pope et al (2002). In addition to the 44 individual level covariates controlled for in Pope et al (2002), Jerrett et al (2005) control for 8 ecologic variables and ozone. While the inclusion of the ecological variable is an improvement over Pope et al (2002), there is still a high likelihood of residual confounding and interactions among pollutants. Furthermore, to the extent that the associations in Pope et al (2002) and Jerrett et al (2005) are not causal ones, the degree of adjustment for confounders may not matter – elimination or reduction PM2.5 would not be expected to parallel its correlation with actual underlying causal factors.

The risk assessment presented in the current draft of the Emissions Reduction Plan for Goods Movement ignores the importance of selecting concentration-response functions from comparable exposure scenarios. The CARB and OEHHA report (2002), acknowledges that, "[w]hen using a C-R Function from an epidemiological study to estimate changes in the incidence of a health endpoint corresponding to a particular change in PM in a location, it is important to use the appropriate value of parameters for the C-R Function. That is, the measure of PM, the type of population, and the characterization of the health endpoint should be the same as or close as possible to those used in the study that estimated the C-R function." (CARB/OEHHA 2002 – Chapter 9, p.9-4) In the 2002 report, CARB assumes that PM2.5 comprises 65% of PM10. However, for the 2006 plan, CARB assumes that PM2.5 is 90% of PM10, and **further assumes that PM2.5 is equivalent in toxicity to diesel PM, something that is not known**. Before action is taken on the ERP, these discrepancies must be addressed and errors rectified. Reviewers of the report are left questioning whether there is an explanation for the discrepancy or if it is simply an error, for example. None of the referenced studies with respect to PM2.5 and premature death assessed diesel exhaust directly or even estimated the degree to which PM2.5 compares toxicologically with diesel exhaust.

The risk assessment method currently applies response rates extracted from studies of cohorts that are not representative of the California population. For a specific location and population estimate to be validly applied to another location and population, background **rates of disease** must be similar between populations; population behavioral characteristics associated with exposure must be similar between locations (e.g., time

spent outdoors); background concentration and composition of PM must be similar between locations; co-pollutants must be similar between locations; and variability between actual exposure and PM monitoring estimates must be similar between locations. In the proposed plan, the authors did not provide comparisons between the Pope et al (2002) study cohort and the California population (present and future) to which the risk models were applied. The American Cancer Society (ACS) cohort (used by both Jerrett et al and Pope et al) is restricted to subjects older than age 30 (and living with someone over the age of 45). It would not be appropriate to apply these rates to the proportion of the population younger than the age of 30 – the younger the population the less appropriate. According to the 2000 census, nearly 50% of the population of California was under the age of 30. While the study results may support an association between PM2.5 and premature death, it would be inappropriate to assume that the results directly apply to the entire California population.

Applying **risk estimates** to different populations, including projected future populations, also assumes that the dose (in this case, composition and concentration of PM) is comparable over time and across geographic areas. The composition and concentration of PM and the concentration of ozone are known to vary both over time and by geographic area. The current plan does not compare the concentration and composition of PM yielding the C-R curve with the concentration and composition of PM expected in CA, and fails to specify the assumptions made to project doses of PM into the future.

Finally, the risk assessment method assumes a linear, no threshold model for estimating risks for each of the outcomes considered in the report. A rational for assuming a linear model was provided in the association between PM2.5 and premature death but not for any of the other exposure/outcome relationships.

In statistical modeling, the linear model is called the "naïve" model, meaning it is the first and simplest model evaluated to describe an association between an exposure and an outcome. Standard practice dictates assessing model fit, and adjusting parameters to include additional or non-linear terms as indicated. EPA guidelines for carcinogens recommend that, when mechanisms of action support it, one or more non-linear models (including threshold and U or J-shaped curves) should be considered when modeling effects in order to set maximum exposure guidelines or regulations. There is no obvious reason why the same approaches should not be applied to non-cancer outcomes.

In conclusion, communicating to the public that a specific number of premature deaths will result from incremental exposure to PM2.5 and that this specific number of premature deaths can be prevented if PM2.5 from a specific source (i.e., diesel exhaust) were reduced is not scientifically defensible and is misleading. The methods on which this approach is based are not scientifically defensible and the results, which are predictably exaggerated, may cause alarm and bias.

Existing OEHHA/CARB Procedures for Evaluating Diesel Emission Were Ignored

In addition to being concerned that the approach used to evaluate the health effects of diesel exhaust is misleading, we are concerned that the risk assessment approach that has been developed previously and recommend for use by CARB and OEHHA was not used.

We saw no explanation for why the risk assessment presented in the ERP for Goods Movement deviated from procedures that would be applied to other sources of diesel emissions. By using a different approach in the ERP, health risks from sources related to Goods Movement cannot be compared to health risks from other sources. In addition to being methodologically different from the standard CARB/OEHHA risk assessment approach, the risk assessment approach used in the ERP differs from the standard OEHHA/CARB risk assessment approach in that it does not have an acceptable risk range or threshold risk level that can be used to judge whether the health risks are of regulatory significance and require control. By relying on DPM as an indicator of the mixture, the risk assessment does not provide information to help identify specific chemicals to be controlled and the degree of control needed for each in order to meet the State's acceptable risk criteria. We recognize that variations of the basic approach used in the risk assessment for the ERP were first used in the draft Port-Wide Risk Assessment for the Ports of Long Beach and Los Angeles. We expressed our concerns at that time and we reiterate them again here. We request a peer-review meeting with CARB, OEHHA and the Business, Transportation and Housing Agency (BTH) to discuss and address our concerns. Do OEHHA and CARB have plans to propose new guidelines on this approach and any use of it in future environmental decision making? Will the existing OEHHA/CARB recommendations for evaluating diesel emissions and components of diesel exhaust be rescinded?

<u>The Risk Assessment Approach in the ERP Appears to Contradict CARB Statements and Positions Taken in Developing the AAQS for PM2.5 and in the Setting of an REL for Diesel Exhaust</u>

The CARB and OEHHA 2002 report described methods used to develop the proposed Ambient Air Quality Standards (AAQS) for PM2.5, of 12 $\mu g/m^3$, which was determined to meet the requirements to, "adequately protect the health of the public, including infants and children, with an adequate margin of safety."

Implicit in the ARB health benefits analysis is the assumption that attainment of the AAQS will insure protection of public safety. For this reason, ARB did not estimate the number of premature deaths attributable to exposure to the AAQS, and did not attempt to attribute a number of premature deaths to PM concentrations emitted from specific sources at levels below the AAQS because they acknowledged that there are "substantial uncertainties in the prediction of health impacts of low-level PM exposure" and sufficient evidence does not support applying the concentration-response functions throughout the range of predicted changes in PM concentrations.

Despite explicit statements in 2002 of significant uncertainties associated with applying the C-R functions to low-level PM concentrations, the proposed risk assessment approach in the draft March 2006 ERP reports the number of premature deaths associated with PM concentrations below the safe levels [AAQS and RELs] established by the State. Having different but parallel approaches to evaluating diesel emissions will lead to the indefensible result that diesel emissions from some sources and under some conditions will have a threshold concentration, while diesel emissions from other sources (i.e., sources related to Goods Movement) will have no threshold.

The Risk Assessment Approach Taken in the ERP Appears to Be Outside of the Standard Regulatory Approach to Evaluating Criteria Pollutants Such As PM2.5

Air pollutants are generally regulated in California either as air toxics or "criteria pollutants." Within each of these categories, there are a number of programs that implement the California Health and Safety Code broad objectives. For example, with respect to stationary sources, air toxics impacts assessments are carried out under the Air Toxics Hot Spots program (AB2588). Criteria pollutants (those ambient pollutants for which health criteria have been established to provide for the protection of the most sensitive fraction of the population with a margin of safety), include such pollutants as PM10, PM2.5, ozone, carbon monoxide, and lead. Of these, and directly relevant to the *Emission Reduction Plan for Ports and Goods Movement Plan,* is the emissions and health impacts of diesel particulate matter (DPM).

Because the State of California has identified DPM as an air toxic, with respect to stationary sources, it is covered within the regulatory framework of AB2588. However, since it is also a particulate, and thus contributes to the ambient loading of particulate in the environment, it is also regulated under those programs addressing the attainment and maintenance of the National Ambient Air Quality Standards (NAAQS) and the State Ambient Air Quality Standards SAAQS)[1].

The South Coast Air Basin largely exceeds the NAAQS for fine particulate (PM2.5), and the South Coast Air Quality Management District (SCAQMD) and CARB are obliged under the Federal Clean Air Act (CAA) to develop and submit a State Implementation Plan (SIP) to the U.S. EPA that provides for the attainment and maintenance of the PM2.5 standard.

Thus, the SAAQS and the NAAQS are both designed to protect the public from the adverse health effects of fine particulate. These standards must (under state and federal law) be regularly re-examined to assure that they reflect current medical knowledge on the relationship between ambient concentrations of these pollutants and the protection of the most sensitive portion of the population (typically children and the elderly). This was recently done at both the state and federal level for PM2.5.

In the last several months, with respect to the Goods Movement sector alone, CARB has begun to develop a third approach to regulating fine particulate matter in the environment. This third approach is reflected in the Goods Movement report by way of relating facility or goods movement segments to specific health effects of fine particulate, and then suggesting that increased fine particulate reductions are needed beyond those

[1] Actually there are several differences between the state and federal ambient standards. In some cases the numerical value is different (the state's is more restrictive). However, the most pronounced difference is that he NAAQS are regulated under the Federal Clean Air Act as standards that must be attained by a calendar date certain, while the California "standards" are would be more appropriately called "goals", since there is no regulatory mandate for the attainment of those standards by any particular date. Further, the Federal program, implemented by way of the State Implementation Plan (SIP) for the Attainment and Maintenance of the NAAQS, includes significant enforcement provisions and penalties for non-attainment of the NAAQS, while the California ambient air quality program has no such provisions for the State ambient standards.

otherwise addressed by the air toxics or ambient air quality planning programs already established.

The Updated Emission Reduction Plan for Ports and Goods Movement in California Does Not Include Sufficient Detail To Support A Peer Review

A nearly universal comment from those who were asked to peer review the December Draft of the ERP was that it did not include enough description and detail to support peer review. While the March 21 version of the report includes more description and detail than was included in the December draft, it still has significant gaps in the description of methods, leaving readers to speculate on approaches and key assumptions. Particularly in the area of emissions estimation, dispersion modeling, and exposure assessment, the report does not provide sufficient detail to allow one to repeat the calculations presented and cited as the basis for the conclusions and recommendations presented in the report.

At the request of Congress, the National Research Council developed guidelines for conducting risk assessment (NRC 1983, NRC 1994) with the specific intent of assuring that risk assessment documents supporting the regulatory decisions did not simply justify a predetermined decision. The need to adhere to these fundamental principles of clarity and transparency in California were affirmed in a process undertaken at the request of the California Legislature (RAAC 1997).

While we support and recognize the need for continuous and simultaneous emission reductions as part of the Goods Movement Action Plan, we do not think the principles of transparency and need for sound science should be, or need to be, sacrificed for the sake of speed. As stakeholders in the Goods Movement Action Plan, we are concerned that we are being asked to accept a plan with a technical basis that has not been described in sufficient detail that peer reviewers can understand it.

As was noted by the authors of the ERP, they had to complete the report in a very short time frame. While this rush no doubt contributed to the short description of methods and assumptions in the text, such working conditions also tend to lead to errors. Even with the expanded explanation provided in the March draft of the ERP, we have not been able to repeat all of the calculations and we have identified some key assumptions that have not been justified. In addition, we have identified several points that appear to be in error. Some examples of important elements of the report where sufficient detail to support peer review or where there may be an error are identified below:

1. CARB did not provide sufficient detail to replicate the calculation of basin-specific averages from the PM10 monitoring data network. A footnote to Table A-11 in Appendix A indicates that, "DPM is derived from receptor modeling results, emissions, and monitoring data", however, CARB did not provide sufficient detail on the methods that were used to make these estimates nor did they provide or sufficiently reference the input data used to derive these estimates.

2. CARB did not provide methodological details regarding how the exposure point concentrations estimated in the POLA/POLB study were extrapolated from the

original modeling domain (20 mi x 20 mi) to an expanded domain (50 mi x 40 mi) nor did they present the original data used as the basis for this expansion.

3. CARB did not provide sufficient detail to replicate their calculation of nitrate and sulfate PM concentrations, secondary organic aerosols concentrations, or ozone concentrations. In addition, CARB did not provide or specifically reference the underlying data from these studies that were the required inputs into their estimation methodologies.

4. It is unclear if/how the emission adjustment factors for port activities in Table IV-3 of Section IV of the main report were applied to CARB's analyses.

5. In several instances, links to references of CARB documents and data indicated to reside on CARB's website did not lead to the reference document or data; instead it resulted in either an error message or a "to be updated" message.

CARB also performed analyses or made assumptions that may have introduced significant uncertainties or potential errors into their calculations of exposure point concentrations. Examples of such analyses and assumptions include:

1. The extrapolation of ISCST3 modeling results from CARB's POLA/POLB study domain (20 mi x 20 mi) to an expanded domain (50 mi x 40 mi) far exceeds the distance to which ISCST3 modeling is appropriate. According to U.S. EPA's Guideline on Air Quality Models ("Appendix W" to Part 51), ISCST3 air dispersion modeling is appropriate for distances less than 50 km (approximately 31 miles). In addition, due to the varied topography and presence of microclimates in the South Coast Air Basin, the use of one meteorological data set to represent the entire Basin (as is required in ISCST3) may result in large uncertainties in predicted exposure point concentrations for areas with significantly different topography and meteorological conditions.

2. In their calculation of basin-specific average PM concentrations, CARB has assumed that the distribution of emissions within each basin is exactly the same from 1990 to 1995 to 2000. Health impacts for years 2005, 2010, 2015, and 2020 were also calculated from PM10 emissions inventory data assuming the same distribution of emissions within each basin in 2005, 2010, 2015, or 2020 as in 1990. CARB does not identify this assumption, provide rationale for the use of this assumption, or quantify the uncertainty associated with this assumption.

3. CARB applied an adjustment factor of 0.1 (coastal) or 0.25 (bays) to DPM emissions emitted directly from off-shore marine sources to adjust for increased dilution and the fraction of emissions that do not reach land due to wind patterns based on modeling performed near the Port of Los Angeles (see Appendix A, Section III.B). However, CARB did not perform sensitivity analyses to evaluate the applicability of modeling results using Los Angeles meteorological conditions to potential meteorological conditions found in the Bay Area and other Air Basins with offshore emissions such as San Diego.

The Updated Emission Reduction Plan for Ports and Goods Movement in California Does Not Include a Complete Discussion of the Uncertainties Associated with the Unit Risk Factor for DPM

According to the principles mentioned above from the NRC and RAAC guiding how risk assessment should be used to support regulatory decisions, a risk assessment should identify and discuss the key uncertainties in the analysis. Among the most important and largest uncertainties associated with performing health risk assessments for DPM are those associated with the State's unit risk factor. In the opinion of the USEPA and a panel of experts convened by the Health Effects Institute (HEI), the uncertainties associated with the epidemiology and the estimation of exposure to diesel emissions were sufficient to cause these organizations to conclude that **a quantitative estimate of cancer potency could not be developed for diesel exhaust as a mixture**. The accepted principles of good risk assessment practice are violated if these important uncertainties are not clearly identified and thoroughly discussed in the risk assessment for the ERP.

Summary

BNSF looks forward to working with CARB in the development of the Goods Movement Plan and in an attendant plan for continuous and simultaneous emissions reductions. We understand the need for rapid progress in the development of our goals and are prepared to continue to work with and support the State in its development of these plans.

We will be providing further comment on the ERP before the April 20, 2006 hearing. In the meantime, we request a meeting with CARB, OEHHA and BTH at the earliest possible date to discuss our concerns.

Sincerely,

Mark P. Stehly
AVP Environment & Research Development