

# Air Toxics Science Advisory Committee

## **Approach for Identifying a Revised ABC for Diesel Particulate Matter: Use of Geometric Mean**

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# ABC for DPM Set in 2006

- The value of 0.1 ug/m<sup>3</sup> was assigned to DPM in 2006, based on toxicity information available at the time and on ATSAC best professional judgment
- The value represented the top of a range of values provided by the World Health Organization in 1996 (*Int’nl Programme on Chemical Safety, Environ. Health Criteria 171: Diesel Fuel and Exhaust Emissions*)
- The OHHEA 1998 value of 0.003 ug/m<sup>3</sup> was available then, but not considered credible by the ATSAC

## Concerns re: Existing Toxicity Information for DPM

- Diesel particulate matter/diesel exhaust is a complex mixture of many chemicals
- There is no way to directly measure DPM
  - Also, components of DPM not unique to diesel exhaust (e.g., EC is also a component of woodsmoke)
- The only cancer-based protective value that's been published for DPM is from OEHHA 1998 – and there is significant controversy in regard to the credibility of this value within the scientific community (Crump ,1991; Health Effects Institute, 1999; comments from McClellan, Ellis, and others to OEHHA ,1997; Morfeld and Spallek, 2015)
- None of the relevant technical articles give a straightforward estimate of DPM toxicity in numerical terms; many authors state that the science is not yet developed enough to assign a protective value to DPM

# Developing a Unit Risk Estimate for DPM

- Given the uncertainty and limited DPM toxicity information, it is challenging to combine the information into a summary risk estimate.
- There are no standard or consensus-based approaches that the ATSAC or DEQ can follow in this case.
- Therefore, a new approach must be developed to define an estimate of risk that will serve as a defensible basis for an ABC.

# Details of Proposed Approach

- A number of epidemiological (epi) studies have obtained results which serve as the basis for Unit Risk Estimates, which is what we need.
- These epi studies more accurately represent the toxicity of diesel to humans:
  - The lung anatomy and physiology of rodents and dogs is substantially different from humans, leading to different deposition and clearance of DPM.
  - The unique toxicological behavior of DPM is attributed to penetration, deposition, and metabolism of the ultrafine particles of diesel in the deep lung (of humans).
  - The short life of rodents, and the high dosing of rodents to induce cancer, differs greatly from the chronic low-level exposures of humans.
- Animal studies provide confirmation of the carcinogenic potential of DPM and support the biologic plausibility of DPM as a complex mixture that differs from the singular effects of its constituent compounds.

# Epidemiological Studies Included in Proposed Approach

~~Harris, 1983~~

Garshick et al., 1987 and 1988

~~McClellan et al., 1989~~

~~Mauderly et al., 1992~~

~~WHO, 1996~~ ———

Will need to be revised

Steenland et al., 1998

~~OEHHA, 1998~~

Stayner et al., 1998

~~USEPA, 1998~~

~~Dawson and Alexeeff, 2001~~

~~Vermeulen et al., 2014~~

# Steps in Proposed Approach

- List all available UREs from epi studies that meet our inclusion and exclusion criteria.
- Convert UREs to concentrations protective of exposure to excess cancer risk at  $1 \times 10^{-6}$ .
- Because the distribution of these data is highly skewed, we log-transform to reduce the influence of extreme values .
  - (The simple arithmetic mean would not be representative of the true mean of the data set, and would likely be biased upward.)
- Obtain the mean of the  $\log_{10}$  concentrations, and then take antilog of result to derive Geometric Mean.
- Back-transform the result (the calculated Geometric Mean) into a normal concentration value.
- The steps in this calculation, and the choice to use the Geometric Mean, are typically used in the analysis of environmental data.

# Summary Points for Proposed Approach

- Calculate the geometric mean of URE values from all human epidemiological (epi) studies presented here.
- Convert the resulting geometric mean value to a geometric-mean-based ABC assuming  $1 \times 10^{-6}$  potential excess carcinogenic risk.
- Because of its basis being a geometric mean, the ABC is robust relative to differences among the individual human epi studies.
- Use of the geometric mean to obtain the DPM ABC, and DPM ABC itself, are policy choices.

# Strength and Potential Limitations of the Approach

## *Strengths*

- The ABC is based on best available studies on human populations
- Concentrations are directly related to  $1 \times 10^{-6}$  excess risk of lifetime death

## *Limitations*

- Limited number of published studies of long-term exposure to diesel exhaust
- Exposure data in these studies is poor
- Residual confounding by smoking may be present
- Healthy worker effect (adult males, long-haul truck drivers, railroad, and miners)

Documents can be provided upon request in an alternate format for individuals with disabilities or in a language other than English for people with limited English skills. To request a document in another format or language, call DEQ in Portland at 503-229-5696, or toll-free in Oregon at 1-800-452-4011, ext. 5696; or email [deqinfo@deq.state.or.us](mailto:deqinfo@deq.state.or.us).