April 2, 2014

Cardno ChemRisk

20 Stanwix Street
Suite 505
Pittsburgh, PA 15222
USA

Phone: 412 281 6900
Fax: 412 281 6999
www.cardno.com

www.cardnochemrisk.com

Dr. Lori White
NTP Designated
Federal Officer National Institute of Environmental Health Sciences
P.O. Box 12233
MD K2-03
Research Triangle Park, NC 27709

Subject: COMMENTS REGARDING NTP EVALUATION CONCEPT: PREGNANCY OUTCOMES ASSOCIATED WITH TRAFFIC RELATED AIR POLLUTION

Dear Dr White:

Cardno ChemRisk, writing on behalf of our client, the Rubber Manufacturers Association, is aware that the NTP's Office of Health Assessment and Translation (OHAT) received a nomination to evaluate emerging children's health issues associated with ambient air that is focused on health outcomes unrelated to respiratory disease, which has been studied extensively. An exploratory literature search and discussions with other research scientists in the federal government have led the OHAT team to focus on pregnancy outcomes and traffic-related pollution.

OHAT indicates that approximately 200 research papers have been published between 2009 and 2012 regarding the topic of pregnancy outcomes and traffic related air pollution and that there is sufficient data to understand whether there is an association between the two. Specifically, the OHAT indicates that the recent literature will be useful in extending the preliminary findings of the Health Effects Institute (HEI), Centers for Disease Control (CDC) and USEPA who have researched the topic previously.

OHAT's proposed approach will include both direct measures of traffic as well as surrogates for traffic related air pollution including environmental gases (i.e., carbon monoxide, ozone, nitrogen oxides, sulfur oxides), generic particulate matter (including PM10, PM2.5, black carbon, and ultrafine, course and total suspended PM), diesel exhaust, benzene and polycyclic aromatic hydrocarbons. OHAT acknowledges that PM exposures are in part traffic related and that the composition varies based on fuel type as well as the PM source; providing the example of course PM which they state is related to road dust containing tire and engine wear. The pregnancy outcomes under consideration will include: congenital malformations, fetal growth, peri- and postnatal mortality, pre-term birth, and pregnancy complications.

Relevant Tire Related Research

Over the last eight years, the Tire Industry Project (TIP) has conducted extensive research of tire road wear particles (TRWP) which fall into the non-exhaust emission category of traffic related pollutants. The purpose of the research has been to fill data gaps in the existing state of knowledge for the purpose of characterization of potential risk to humans and the environment. For airborne TRWP, this research has included both toxicity evaluations and quantification of human exposure to TRWP through inhalation of the outdoor ambient air (Kreider et al., 2011, Kreider et al 2012, and Panko et al 2013). It is unknown whether this research has been included in the 200 papers that OHAT has identified, therefore, RMA would like to notify USEPA as to their relevance.

Although there is not concurrence in the scientific community regarding the importance of one constituent of traffic related air pollution over another with respect to health effects, there are many publications that indicate there are differences in toxicity profiles (HEI, 2013). This was also observed in the toxicity studies of TRWP. In one study, the relative toxicity of TRWP with respect to cardiopulmonary endpoints was examined through a rodent intratracheal instillation study design that compared the effects from TRWP to negative controls (air only and titanium dioxide) and positive controls (crystalline silica and diesel exhaust particulate) (Kreider et al., 2011). The results of this study indicated that TRWP responded in a manner similar to the negative controls and is a less potent inhalation toxicant than diesel exhaust or crystalline silica. Similarly, a sub-acute rodent inhalation study was conducted with TRWP and no adverse effects were observed at any test concentration up to the maximum of 112 µg/m^3 TRWP (Kreider et al., 2012). The OHAT has not yet described what their hypothesis is with respect to the potential mechanism of action responsible for the adverse pregnancy outcomes reported in the literature. If, however, the pro-inflammatory mechanisms that have been associated with the cardiopulmonary effects are related, TRWP is less likely than other traffic related pollutants to be associated with those outcomes.

With respect to exposure of humans to airborne TRWP, a study was conducted in three countries (France, US and Japan) to quantify TRWP in the PM10 fraction of ambient air (Panko et al., 2013). In this study, PM10 air samples were collected roadside (<300 m from road) in areas with known traffic and at locations near where people reside, work and recreate. The air samples were collected in a wide variety of environments from rural areas to megacities (i.e., Paris). Results indicated that TRWP concentrations in the PM10 fraction were low with averages ranging from 0.05 to 0.70 µg/m^3, representing an average PM10 contribution of 0.84%. A new study is underway to quantify TRWP in the PM2.5 fraction of ambient air and will be conducted in locations where traffic has been identified through source apportionment to be a significant contributor to the PM2.5 levels. Specifically, the study will be conducted in London England, Los Angeles California and Yokohama, Japan and the study design will incorporate distance from the road as a factor in the evaluation of the concentrations. We anticipate that the data from this study will be available by the end of 2015.

Closing

Because the OHAT literature search was aimed at updating information already published by HEI and others it only included the years 2009 – 2012. As such, they may not have identified the Kreider et al., 2012 and would not have included Panko et al., 2013 in their search. RMA believes that these studies would be useful to OHAT in answering their key questions and have included them for your review. Please let me know if you have any questions regarding the TIP research studies regarding TRWP.

Sincerely,

[Redacted]

Julie M. Panko
Principal Health Scientist
for Cardno ChemRisk
Direct Line +1 412 694 7045
Email: julie.panko@cardno.com

References

HEI (2013). HEI NPACT Review Panel. 2013. Executive Summary. HEI's National Particle Component Toxicity (NPACT) Initiative. Health Effects Institute, Boston, MA.

Kreider, M.L., J.M. Panko, J.D. McDonald, B.L. McAtee, B.L. Finley, and J. Seagrave. 2011. Effects of Intratracheal Instillation of Tire and Road Wear Particles (TRWP) and Tread Particles (TP) on Inflammation and Cytotoxicity in Rat Lung: A Comparative Toxicity Study. Presented at 2011 Society of Toxicology Meeting, Washington, D.C., March 6-10, 2011. http://www.wbcsd.org/Pages/EDocument/EDocumentDetails.aspx?ID=54&NoSearchContextKey=true

Kreider, M.L., M. Doyle-Eisele, R.G. Russell, J.D. McDonald, and J.M. Panko. 2012. Evaluation of potential for toxicity from subacute inhalation of tire and road wear particles in rats. Inhal Toxicol. 24(12):907-917

Panko, J.M, J. Chu, M.L. Kreider, and K.M. Unice. 2013. Measurement of airborne concentrations of tire and road wear particles in urban and rural areas of France, Japan, and the United States. Atmosph Environ.72:192-199.