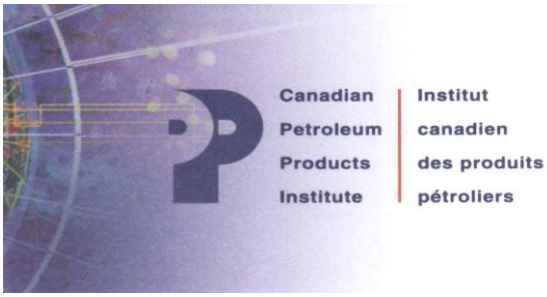


Sept. 29, 2009

Ms. Minnie de Jong
Manager, Human Toxicology and Air Standards Section
Standards Development Branch
Ministry of the Environment
40 St. Clair Avenue West, 7th Floor
Toronto Ontario M4V 1M2

Re: ON Reg. 419 Nickel and Nickel Compounds Air Standard EBR 010-7188

Dear Ms. de Jong:

This letter contains input from the Canadian Petroleum Products Institute (CPPI) in response to the EBR Posting 010-7188.

CPPI is the national association representing the interests of the downstream petroleum industry for all aspects of petroleum refining, distribution, transportation and marketing of petroleum products. In the province of Ontario, CPPI members include Imperial Oil, NOVA Chemicals, Shell Canada, Suncor and Ultramar. This includes operation of the 6 petroleum refineries processing about 380,000 barrels per day of crude oil, and as well, the operation of a substantial portion of the distribution and marketing infrastructure in the province.

CPPI members have maintained and demonstrated a long-standing commitment to improving environmental performance and helping protect Ontarians from being exposed to toxic substances from their operations, as well, in partnering with MOE to provide meaningful input on new developments.

From reviewing the MOE proposed Nickel annual air standard of 0.02 µg/m^3 for Nickel and Nickel compounds in the PM_{10} size fraction, and 0.04 µg/m^3 in the TSP (Total Suspended 124 Particulate) , it appears that MOE has chosen the approach developed by the EU Working Group, which represents most recent science and takes into account both non-cancer and cancer effects. However, the substantial science based input and arguments made by CPPI in our April 3, 2009 submission to the science consultation document, that would credibly support a higher air standard were not accepted. This is disappointing. CPPI draws your attention to our April 3rd input, as well has outlined further specific scientific input for the MOE to reconsider. Based on this science basis, CPPI has recommended different annual, short-term AAQC values, and URTs.

Nickel Annual AAQC

An annual AAQC between 50 and 160 ng Ni/m^3 (0.05 to 0.160 µg/m^3) would be protective of human health since it is based on: (1) the most sensitive endpoint for toxicity, (2) the most sensitive species (rats), and (3) the nickel compounds which are more potent with regard to pulmonary toxicity (water soluble nickel compounds).

1) The EU Working Group uses the NTP Nickel Sulfate Hexahydrate study to derive a LOAEL of 60 µg Ni/m^3. However, this NTP study established a NOAEL of 30 µg Ni/m^3 in male rats, although a marginal (not significant) increase in the rate of fibrosis occurred in the low exposure group. The study does not support a causal relationship between the non significant increase in the rate of fibrosis with exposure to nickel sulfate hexahydrate because there is no increase in chronic active inflammation (a condition related to the formation of fibrosis) in the group exposed to 60 µg Ni/m^3 compared to the control group. In addition, analysis of control data from 56 NTP studies demonstrated a historical control range of response for lung fibrosis from 0/50 (0 %) to 8/50 (16 %) animals. The NOAEL of 30 µg Ni/m^3 is also supported and used by the California EPA. Starting from A NOAEL of 30 µg Ni/m^3 and using uncertainty factors of 6 for exposure time, 3-10 for interspecies differences and 10 for intraspecies differences, the resulting value is 50 – 160 ng Ni/m^3.
2) Comparing the exposure concentrations that result in adverse effects in rats to the (10 to 100-fold higher) concentrations that workers are exposed to in the workplace without any adverse effects indicates that rats are more sensitive than humans to the respiratory effects of inhaled nickel compounds. Thus, the data support a toxicodynamic factor of 1, resulting in a total factor of 3 (i.e., the default factor for toxicokinetics) for interspecies extrapolation.
3) The NTP nickel sulfate hexahydrate study should be chosen as the key study because results of animal studies show that the insoluble nickel compounds present in ambient air (e.g., nickel oxides) are less irritating than nickel sulfate hexahydrate at equal concentrations of nickel.

Based on the above scientific basis, CPPI recommends an annual AAQC for Nickel and Nickel compounds in the range of 0.05 to 0.160 µg/m^3 for nickel and nickel compounds in the PM_{10} size fraction.

Nickel ½ hour and 24 hour AAQC

- Pulmonary fibrosis is a health effect that may occur upon chronic exposure to dust (e.g. metal dust, wood dust, etc). Calculating a short-term standard based on an effect that is the result of long-term exposure, is scientifically indefensible.
- Soluble nickel compounds appear to be the greatest concern for acute health effects. In contrast to the long half-life of the insoluble forms of nickel in the nasal mucosa, the elimination half-life of Ni^{2+} in the plasma is 1-2 days in mice (California OEHHA, 2008).
- The California OEHHA, based their 1-hour Inhalation reference exposure level (REL) of 6 µg Ni/m^3 on small decrements in acute airway function tests in asthmatics upon inhalation of 0.3 mg/m^3 $NiSO_4 \cdot 6H_2O$ (LOAEL 67 µg Ni/m^3). This is an appropriate basis for a short-term standard.

Based on the above scientific basis, CPPI recommends that the Nickel half-hour standard be changed to 6 µg/m^3 for nickel and nickel compounds in the PM_{10} size fraction, and 12 µg/m^3 in the TSP fraction. Subsequently the Nickel 24 hour standard be changed to 2 µg/m^3 (based on 6/3) for nickel and nickel compounds in the PM_{10} size fraction, and 4 µg/m^3 in the TSP fraction.

Nickel Upper Risk Threshold (URT)

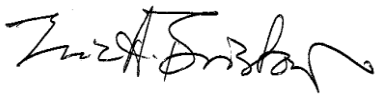
- Consistent with the science points above, the URT should be based on acute health effects as presented by California OEHHA and based on the one hour Inhalation Reference Exposure Level (use for half hour standard).
- **Since the REL is 6 µg/m^3, the half hour URT should be 10 times that value, or 60 µg/m^3 (for nickel and nickel compounds in the PM_{10} size fraction, and 120 µg/m^3 in the TSP fraction). The 24-hour URT should subsequently result in a value of 20 µg/m^3 for nickel and nickel compounds in the PM_{10} size fraction, and 40 µg/m^3 in the TSP fraction.**

Reference

- California Office of Environmental Health Hazard Assessment (OEHHA), 2008. TSD for non-cancer RELs. http://oehha.ca.gov/air/hot_spots/

We welcome the opportunity to meet with you for further discussion on the CPPI input, in support of developing an appropriate and realistic air standard for Nickel.

Sincerely,



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Cc Mr. Carl Griffith, ADM, Environmental Sciences and Standards Division, MOE
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Ms. Faith Goodman, Vice-President Ontario Division, CPPI