

# CN COUNCIL

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April 22, 2013

Ms. Cynthia Oshita  
Office of Environmental Health Hazard Assessment  
P.O. Box 4010, MS-19B  
Sacramento, California 95812-4010

VIA EMAIL: [P65Public.Comments@oehha.ca.gov](mailto:P65Public.Comments@oehha.ca.gov)

**RE: Notice of Intent to List (NOIL) Hydrogen Cyanide and Cyanide Salts Under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65)**

Dear Ms. Oshita:

The Cyanide (CN) Council is writing in response to the Office of Environmental Health Hazard Assessment's (OEHHA) March 22, 2013 Notice of Intent to List (NOIL) Hydrogen Cyanide (HCN) and Cyanide (CN) Salts under the Safe Drinking Water and Toxic Enforcement Act of 1986 (Proposition 65 or Prop 65). The CN Council<sup>1</sup> represents the major manufacturers of hydrogen cyanide (HCN; CAS 74-90-8), various CN salts and other cyanide related compounds. The CN Council previously provided information to OEHHA in August 2011 in response to the May 13, 2011 Request for Relevant Information on hydrogen cyanide and cyanide salts. The CN Council remains very interested OEHHA's activities on HCN and CN salts and this NOIL in particular.

While the CN Council continues to believe that the toxicology information provided in our earlier submissions is adequate to cause OEHHA to reconsider its listing of HCN and CN salts as Prop 65 male reproductive toxicants, these comments will focus on the proposed listing itself. In particular, the ill-defined nature of the chemicals that OEHHA is proposing to place on the Prop 65 list and use of a U.S. Environmental Protection Agency (EPA) Integrated Risk Information System (IRIS) Toxicology Profile under the authoritative bodies (AB) listing mechanism.

## **I. Listing Does Not Adequate Describe the Substances to Be Included on Prop 65**

This proposed listing is stated to cover hydrogen cyanide and cyanide salts. While hydrogen cyanide is a discrete substance, the category "cyanide salts" is not defined at all. Such a listing leaves far too much ambiguity as to what OEHHA proposes to cover under Prop 65, and will thusly create enormous problems for those California businesses that must implement this regulation. Further, as discussed in the next section, it does not appear that U.S. EPA has "formally identified" all cyanide salts as causing reproductive toxicity.

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<sup>1</sup> Members of the CN Council include Ascend Performance Materials LLC, Cornerstone Chemical Company, The Dow Chemical Company, E.I. du Pont de Nemours and Company, Evonik Corporation, INEOS Nitriles and Lucite International.

Cyanide sources are both natural and anthropogenic, and cyanide may occur in a wide array of different chemical forms (EPA 2010, ATSDR 2006, ECETOC 2007). Cyanide is ubiquitous in the environment due to its natural occurrence in plants and as a result of biomass burning and other forms of combustion. Given this situation, OEHHA must clearly state exactly which chemical(s) it is proposing to include on the Prop 65 list in order to create a regulation that can actually be implemented by California businesses. As it is, this proposed listing creates an unmanageable universe of potential chemicals, businesses and scenarios that could be subject to Prop 65 regulation and enforcement.

**2) EPA IRIS Assessment is Not Sufficient to Meet the AB Listing Mechanism for Hydrogen Cyanide or the Entire Class of “Cyanide Salts”**

The Authoritative Bodies (AB) provision under Article 3 §25306 requires that OEHHA determine “which chemicals have been formally identified by an authoritative body as causing cancer or reproductive toxicity.” In using an EPA IRIS assessment, which is not specifically targeted towards the identification of reproductive toxicants, under the AB listing mechanism, OEHHA should only consider those chemicals that have been “formally identified” as causing reproductive toxicity. A close review of the IRIS assessment that forms the basis for this proposed listing indicates that only studies on sodium cyanide (NaCN) were identified by EPA as causing male reproductive effects. In fact, EPA reviewed a number of studies on other cyanide compounds (e.g., potassium cyanide and acetone cyanohydrin) and did not “formally identify” that these compounds cause male reproductive effects.

OEHHA noted when it put forward this proposed listing, that the key study identified by EPA was the National Toxicology Program (NTP) 90-day drinking water study of NaCN in rats and mice. In addition, OEHHA noted that EPA also identified a study by Kamalu of NaCN in male mongrel dogs as a supporting study. The CN Council can find no other formal identification of any other cyanide compound by EPA in the IRIS assessment as causing male reproductive effects. Further, EPA actually notes in the IRIS assessment that “the mode of action of these reproductive effects is not well established.” As we have previously noted, the CN Council does not agree that these data were sufficient for EPA to make the judgment that it did. Regardless, given the limitation of these data and the manner in which EPA summarized this information in the IRIS assessment, it would be inappropriate for OEHHA to consider the AB listing mechanism for any substances beyond NaCN.

EPA’s derivation of an RfD for CN<sup>-</sup> based on the NTP (1993) study is not a formal identification by EPA that HCN and all CN Salts are male reproductive toxicants. The RfD is a numerical risk threshold, not a basis for a formal classification by an AB. In fact, the IRIS assessment considered a variety of studies and endpoints in the derivation of the RfD. Further, it should be noted that for the derivation of the RfC (inhalation risk concentration), the EPA used an HCN study (El Ghawabi) of human workers exposed for 5-15 years in the electroplating industry. The critical effect from this study was “thyroid enlargement and altered iodide uptake,” not reproductive effects. At no point in the IRIS review of the HCN database does EPA identify any studies or endpoints related to reproductive toxicity. It is worth noting that HCN is a gas and, as such,

inhalation is the primary route of exposure. Thus the RfC, based on thyroid effects, and not the RfD will generally be more relevant to evaluating the environmental hazards/risks of HCN.

The AB (U.S. EPA) has simply not formally identified HCN and most CN salts, aside from NaCN, as reproductive toxicants. OEHHA appears to side step this apparent shortcoming in the using the IRIS assessment under the AB listing mechanism, by noting that the IRIS assessment mentions “it is possible the observed reproductive effects following exposure to cyanide may be mediated through decreases in thyroid hormones mediated through the cyanide metabolite thiocyanate.” [emphasis added] However, in the same paragraph of the IRIS assessment EPA also states that the “the mode of action of these reproductive effects is not well established.” Further, EPA notes in the IRIS assessment that there were no observed thyroid effects in the NTP studies from which it identified these reproductive effects for NaCN. In the end, EPA states, “though some information supports this hypothetical mode of action that reproductive effect observed in the NTP (1993) study may be due to alterations in thyroid function due to exposure to cyanide, specifically the cyanide metabolite thiocyanate, uncertainty exists due to the lack of any measurement of indicators of thyroid function, such as thyroid hormones (TSH, T3, T4) or thyroid weight.” [emphasis added] Having EPA say that something is hypothetically possible, though uncertainty exists, is hardly the formal identification requirement that must be met for OEHHA to apply the effects noted by EPA for NaCN to HCN and all CN salts.

For OEHHA to use the IRIS assessment to pursue this NOIL for HCN and all CN salts is not in keeping with the regulation governing the AB listing mechanism.

The CN Council is currently planning additional research on the male reproductive toxicity of sodium cyanide in order to address the significant deficiencies in the NTP drinking water studies in regards to their interpretability on the male reproductive endpoint. The CN Council strongly urges OEHHA to abandon this currently proposed AB listing and to refer this case to the Developmental and Reproductive Toxicant (DART) Identification Committee for future review. Once this additional research is available, the DART committee can consider it along with the information previously identified by EPA and other data to determine which, if any, cyanide compounds should be considered for the Prop 65 list.

The CN Council appreciates your consideration of these comments, please let me know if you have any questions or need any additional information. I can be reached at (202) 419-1500 or at [ajagues@regnet.com](mailto:ajagues@regnet.com).

Sincerely,



Andrew M. Jaques  
Deputy Executive Director