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ENVIRONMENTAL PROTECTION**

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MEMORANDUM

TO: Department Waste Program Administrators
Department Solid Waste Engineers

FROM: Jorge R. Caspary, P.G.
Director, Division of Waste Management 

SUBJECT: Monitoring and Evaluation of Ammonia in Ground Water at Solid Waste Management Facilities
SWM-13.10

DATE: December 3, 2012

Ammonia in ground water may be monitored and reported as part of a ground water quality monitoring plan, typically in relation to a Department permitted activity, or as part of corrective action for site rehabilitation under Chapter 62-780, Florida Administrative Code (F.A.C.). Ammonia is typically included as a parameter in the ground water monitoring plans for landfills and other waste management facilities.

While ammonia has often been included as a parameter in ground water monitoring plans, ammonia itself does not have a numeric water quality standard for the protection of ground water under Chapter 62-520, F.A.C. Currently, ammonia is identified in Chapter 62-777, F.A.C, as a, "minimum criteria systemic toxicant," and it has a ground water cleanup target level (CTL) of 2.8 mg/L. This ground water CTL was calculated and adopted based on a previously published Agency for Toxic Substances and Disease Registry (ATSDR) Minimal Risk Level (MRL) for an ammonia oral reference dose (RfD). On June 8, 2012, the Environmental Protection Agency (EPA) issued a draft toxicological review of ammonia in support of summary information on the Integrated Risk Information System (IRIS). At the request of the Department, on June 13, 2012, the Center for Environment and Human Toxicology (Center) at the University of Florida provided comments on the draft toxicological review. A copy of these comments is attached to this memorandum for reference. Based on their review, the Center commented:

The oral MRL used to calculate groundwater and soil CTLs is no longer supported by ATSDR in its current Toxicological Profile for ammonia, and the EPA in this Toxicological Review has also concluded that current data are inadequate to support oral RfD development. Dropping the oral RfD from Chapter 62-777, F.A.C. would eliminate the groundwater CTL

and could substantially change the soil CTL, which would then be based upon inhalation exposure only.

As a ground water CTL, the ammonia concentration of 2.8 mg/L is not a Department standard as defined under s. 403.803(13), Florida Statutes. While the Department has not adopted an ammonia standard for the protection of ground water under Chapter 62-520, F.A.C., related nitrogen bearing compounds are regulated for protection of ground water quality (e.g., nitrite at 1 mg/L as N, and total nitrate plus nitrite at 10 mg/L as N). Also, Chapter 62-302, F.A.C., does have ammonia and other nitrogen related standards for protection of surface waters (e.g., un-ionized ammonia at 0.02 mg/L as NH₃ and total nitrogen at concentrations to prevent nutrient impacts).

Since ammonia is not regulated as a specific ground water quality standard, ammonia concentrations have been evaluated based on the minimum criteria for ground water adopted under Rule 62-520.400, F.A.C. The minimum criteria for ground water, in part, states that, "All ground water shall at all places and at all times be free from... discharges in concentrations which, alone or in combination with other substances, or components of discharges... are carcinogenic, mutagenic, teratogenic, or toxic to human beings." During technical reviews, the ammonia ground water CTL has been used as guidance for evaluating whether concentrations in ground water exceed the minimum criteria and whether there may be ground water quality concerns.

Since the ATSDR has removed the oral RfD for ammonia from its MRLs publication¹, there is no longer a supported toxicological basis for relying on the ammonia ground water CTL as an indicator of ground water quality, since the CTL was calculated from ATSDR's now withdrawn technical information. The presence of dissolved nitrogen species in ground water, such as nitrate and nitrite, may still be evaluated. Similarly, ammonia in ground water may still be a concern where migration of a plume and ammonia seepage may adversely affect surface waters of the state.

Based on this new information from the ATSDR, EPA, and the review comments from the Center, it is likely the Department will ultimately propose rulemaking to eliminate ammonia as a ground water CTL in Chapter 62-777, F.A.C. EPA's pending technical review of its June 2012 draft will also address whether the inhalation reference concentration (RfC) should be increased which would in turn affect the Department's adopted soil CTL. Thus, once EPA has finalized its review, rulemaking will likely be appropriate to consider changes to the ammonia cleanup target

¹ February 2012, Agency for Toxic Substances and Disease Registry, Minimal Risk Levels; from http://www.atsdr.cdc.gov/mrls/pdfs/atsdr_mrls_february_2012.pdf; on November 19, 2012.

levels in Chapter 62-777, F.A.C. EPA's final adoption of its June 2012 draft toxicological review of ammonia is not expected until mid 2014, if there are no delays.²

Consequently, given the ATSDR's removal of the oral RfD MRL for ammonia, which is not expected to be affected by EPA's pending review, we are now providing the following specific guidelines for monitoring and evaluation of ammonia concentrations in ground water at solid waste management facilities:

1. Department solid waste staff should no longer rely on the ground water CTL as being a suitable toxicological reference for evaluating the significance of ammonia concentrations in ground water.
2. Department solid waste staff should not enforce ammonia as a minimum criteria contaminant for ground water at permitted or non-permitted solid waste management facilities, unless there are sufficient scientific reasons to believe the ground water is discharging to surface waters and likely to cause a violation of surface water standards for ammonia.
3. For permitted and non-permitted solid waste management facilities where the facilities are being required to conduct evaluations for which ammonia is the only parameter of concern and where the ground water is not expected to discharge to surface waters at concentrations exceeding surface water quality standards, then Department solid waste staff should cease requiring those evaluations and terminate any associated enforcement actions.
4. Where there are ongoing corrective actions at permitted solid waste management facilities for which ammonia is the sole parameter of concern, Department staff should review related nitrogen bearing compounds (e.g., nitrate, etc.) and whether there is a potential for ammonia related surface water impacts when determining whether further corrective action is warranted, or if the associated ground water corrective action should be completed or terminated. While corrective actions solely for ammonia in ground water would no longer be pursued unless needed to prevent surface water quality impacts, Department staff should continue to evaluate whether other nitrogen compounds may be a concern when reviewing existing water quality data.

Sound professional judgment must be used to determine whether ground water from a solid waste management facility is discharging to surface waters with ammonia concentrations that exceed the un-ionized ammonia surface water quality standard, or to prevent such exceedances from ground water seepage in the future. Care should be taken to differentiate whether ammonia

² IRISTrack Detailed Report, Ammonia Assessment Milestones and Dates; from http://cfpub.epa.gov/ncea/iristrac/index.cfm?fuseaction=viewChemical.showChemical&sw_id=1106; on November 20, 2012.

concentrations detected in waters of the state are associated with a landfill or other waste disposal activity, or whether they may be associated with other contributors of ammonia such as agricultural activities or urban runoff. Ammonia concentrations in soil may still be evaluated based on the soil CTL since the EPA review does not propose eliminating the inhalation RfC. However, the Department's calculated soil CTL may change depending on the outcome of EPA's pending review.

Caveat

This guidance memorandum does not constitute a rule of the Department. It is intended solely as internal guidance to Department staff, and is not intended to create additional requirements for the regulated community or to affect the rights of substantially affected parties to any agency decision. Please do not cite any part of this memorandum as though it were a standard, rule, or requirement.

JRC/JAC/rt

Attachment: As Noted.

June 13, 2012

Ligia Mora-Applegate
Bureau of Waste Cleanup
Florida Department of Environmental Protection
2600 Blair Stone Road
Tallahassee, FL 32399-2400

Re: IRIS Toxicological Review of Ammonia and Toxicity Values for Risk Assessment

Dear Ms. Mora-Applegate:

We have reviewed at your request the draft *Toxicological Review of Ammonia (CAS No. 7664-41-7) in Support of Summary Information on the Integrated Risk Information System (IRIS)*. This document was prepared by the National Center for Environmental Assessment (NCEA) of the U.S. Environmental Protection Agency and is dated June 2012. This document is available for public comment and will soon be scheduled for review by the EPA Science Advisory Board. With input from external review, the Toxicological Review will be finalized and the proposed ammonia toxicity value will be posted on IRIS.

As a general comment, this toxicological review differs from previous documents of this type by being shorter with more emphasis on interpretation of the available literature rather than providing detailed, sometimes redundant text summaries of the studies. In order to be more efficient in the presentation of the relevant toxicological literature, greater use is made of summary tables and figures. Greater effort is also made to explain the basis for EPA's decisions regarding the science to make the assessments as transparent as possible. These changes are part of an effort by NCEA to improve the toxicological reviews in support of IRIS, making them more readable and useful. They have been made as part of an overall program to improve IRIS in response to recommendations by the National Academy of Science. A description of EPA's plans to improve IRIS and timetable were provided in a recent update to Congress (*EPA's Integrated Risk Information System Program. Progress Report and Report to Congress*, June 2012). The new format facilitated our review and we are supportive of this and other changes in the IRIS process.

Currently, IRIS has an inhalation reference concentration (RfC) of 0.1 mg/m³ based upon an occupational exposure study by Holness et al. (1989). That study identified a no-effect concentration of 2.3 mg/m³ where decreased pulmonary function and changes in subjective symptomatology seen at higher concentrations of ammonia were not observed. An uncertainty factor of 30 was applied based upon a factor of 10 for protection of sensitive subjects and a factor of 3 for toxicity database deficiencies. No oral reference dose (RfD) is listed, and no evaluation of potential carcinogenicity is provided.

The draft Toxicological Review proposes a somewhat higher inhalation RfC of 0.3 mg/m³. The critical study is the same Holness et al. (1989) occupational epidemiology study and a NOAEL/LOAEL approach is also used for the proposed new RfC with two differences:

- 1) A different NOAEL concentration from the study is used. In the previous assessment, a NOAEL of 6.4 mg/m³ was selected from the estimated mean concentration for the entire exposed group and used to derive an adjusted NOAEL (for continuous exposure) of 2.3 mg/m³. In the current draft assessment, the lower bound of the high exposure group of 8.8 mg/m³ is selected as the NOAEL because the frequency of pulmonary symptoms was not statistically different from the frequency in the lower exposure groups. From this NOAEL, an adjusted NOAEL of 3.1 mg/m³ is calculated.
- 2) A UF of 10 is chosen for protection of sensitive populations, but the additional database factor of 3 in the previous assessment has been eliminated.

Acute exposures to high concentrations of ammonia clearly have adverse effects on the gastrointestinal tract in both humans and animals due to corrosive actions. Evidence for gastrointestinal damage from chronic exposure to lower concentrations is not quite as clear. The draft Toxicological Review points out that formation of ammonia from urease catalysis of urea by *H. pylori* is associated with a variety of gastrointestinal diseases, including chronic gastritis, gastric ulcers, and stomach cancer. This provides biological plausibility for adverse effects on the GI tract from chronic ammonia exposure. Further, animal studies show consistent evidence of changes in gastric mucosal morphology associated with ammonia in drinking water. However, these animal studies did not show lesions in the stomach. The Toxicological Review indicates that gastric effects may be a hazard from ammonia, but indicates that there are questions concerning the adversity of the gastric mucosal findings in rats. It concludes that, "the available oral database for ammonia was considered insufficient to characterize toxicity outcomes and dose-response relationships." (page 2-1). This decision not to develop an oral RfD is consistent with the previous assessment. It is interesting to note that the absence of gastric effects in rats exposed to high levels of ammonium chloride (up to 1,200 mg/kg-day for 130 weeks in the diet) is taken as evidence for the absence of GI effects of ammonia (page 1-17), when the Preface clearly states that the toxicity of ammonia and ammonia salts (including ammonium chloride) are expected to be different and that "... ammonium salts were not used in the identification of effects or in the derivation of reference values for ammonia and ammonium hydroxide."

The status of evaluation of potential carcinogenicity of ammonia is essentially unchanged from the previous assessment in 1991. Reliable data with which to assess potential ammonia carcinogenicity are still unavailable. A study of mice exposed to ammonium hydroxide in drinking water (Toth, 1972) concluded that tumor incidence was not increased, but provided no data on tumor incidence in control animals except mammary gland tumors in female C3H mice. Studies in rats (Tsuji et al., 1992; 1995) suggest ammonia in drinking water may be a tumor promoter, but provide no information on possible carcinogenic effects of ammonia itself.

Although the Toxicological Review and its proposed toxicity value (inhalation RfC) are not yet final and are subject to change, it is important to consider implications of their acceptance on cleanup criteria for ammonia in Florida. Chapter 62-777, F.A.C. contains cleanup target levels (CTLs) for ammonia for both groundwater and soil. These are based upon the current IRIS RfC of 0.1 mg/m³ and an oral RfD based upon an ATSDR Minimum Risk Level (MRL). A 3-fold increase in the inhalation RfC could result in an increase in the soil CTL, but would have no effect on the groundwater CTL, which is based upon ingestion only. In the event that Chapter 62-777, F.A.C. is re-opened, it may be worthwhile to re-visit the oral RfD for ammonia. The oral MRL used to calculate groundwater and soil CTLs is no longer supported by ATSDR in its current Toxicological Profile for ammonia, and the EPA in this Toxicological Review has also concluded that current data are inadequate to support oral RfD development. Dropping the oral RfD from Chapter 62-777, F.A.C. would eliminate the groundwater CTL and

could substantially change the soil CTL, which would then be based upon inhalation exposure only.

Please do not hesitate to contact us if you have any questions regarding this Toxicological Review or its implications.

Sincerely,



Roxana E. Weil, Ph.D.



Leah D. Stuchal, Ph.D.

References

- Holness DL, Purdham IT, and Nethercott IR (1989). Acute and chronic respiratory effects of occupational exposure to ammonia. *AIHA J.* 50:646-650.
- Toth B (1972). Hydrazine, methylhydrazine and methylhydrazine sulfate carcinogenesis in Swiss mice. Failure of ammonium hydroxide to interfere in the development of tumors. *Int. J. Cancer* 9:109-118.
- Tsuji M, Kawano S., Tsujii S, Nagano K, Ito T, Hayashi N, Fusamoto H, Kamada T, Tamura K (1992). Ammonia: a possible promoter in *Helicobacter pylori*-related gastric carcinogenesis. *Cancer Lett.* 65:15-18.
- Tsuji M, Kawano S, Tsujii S, Takei Y, Tamura K, Fusamoto H, Kamada T (1995). Mechanism for ammonia-induced promotion of gastric carcinogenesis in rats. *Carcinogenesis* 16:563-566.