



The Fertilizer Institute

Nourish, Replenish, Grow

June 2, 2014

Public statement on behalf of The Fertilizer Institute, to the Scientific Advisory Board Chemical Assessment Advisory Committee (CAAC) for the review of the Draft IRIS Ammonia Assessment.

Good Afternoon.

I am providing remarks today on behalf of The Fertilizer Institute (TFI). We appreciate the opportunity to address members of the Committee for the review of the Draft IRIS Ammonia Assessment. TFI commented on the 2012 version of the assessment you are reviewing and welcome the opportunity to again contribute to the review process.

We would first like to address General Charge Questions 1 and 3:

In the latest draft, Appendix G, EPA responds to public comments and in some but not all instances has made appropriate changes or provided clear rationale for not doing so. While the EPA have indicated that they have implemented the 2011 NAS recommendations, we do not agree that this implementation is sufficiently encompassing. Comments submitted by the public and stakeholders are the result of considerable thought and consideration. Failure to respond with specific justification for their dismissal fails to provide transparency in the scientific reasoning behind the decision, an omission which we believe defeats the intent of the NAS recommendations. We would therefore ask that the reason for dismissal of such input be provided in order to gain insight to the reasoning of the committee. We believe that the May 2014 NAS IRIS process review document supports this contention.

The second point we would like to address speaks to Charge E. 1. Inhalation Reference Concentration (RfC):

We are asked to comment on whether the evaluation and selection of studies and effects for the derivation of the RfC is scientifically supported and to identify and provide the rationale for any other studies or effects that should be considered. In response to this, we would suggest that the Committee needs to review and evaluate specifically the findings of the Committee on Acute Exposure Guideline Levels, Committee on Toxicology of the National Research Council of the National Academy of Sciences which in 2008 derived an AEGL-1 for Ammonia which specifically selected a significantly different point of departure (30 ppm). Further, this Committee determined that several uncertainty factors, which are identical to those this IRIS committee must review, were unnecessary:

- interspecies uncertainty was not necessary because the value is based on human data,
- a time adjustment factor was not necessary because the earliest health effect of ammonia is irritancy which is not lowered in threshold with time, and

- because the data reviewed included non-atopic and atopic subjects, including asthmatics, a correction factor for sensitive individuals in the population was not merited.
- As a result, the AEGL-1 value very strongly duplicates the findings we would expect to see for a chronic human RfC.

It is interesting to note that while both organizations seek to understand the toxic effects of ammonia, the AEGL review by the NRC Committee reviewed 82 documents and derived definitive conclusions regarding time weighting, sensitive sub-populations and reliance on human vs animal data which eliminated the need for the use of uncertainty factors. The EPA reviewed 173 documents of which only 14 coincided with the NRC review. Perhaps because of the review of different data sets, this dichotomy is not surprising, but we believe that the extensive use of uncertainty for deriving RfC reflects perhaps only data from specific points of view which limits the agency's ability to derive a definitive and not uncertainty filled RfC.

We would also like to note that other agencies of the U.S. Government specifically tasked with human health protection such as OSHA, NIOSH as well as individual States and international Government Agencies in Canada, and Europe align much more closely with the decision of the AEGL review committee for their occupational standards for health protection.

Despite the fact that the AEGL review was for the production of AEGL's vs RfC's, the logic of the data selection and rational in the application of an overall uncertainty factor of 1 merits review. Lastly, and referring to my first comment, if the AEGL Committee logic in the application of uncertainty factors and POD is rejected, it would be elucidating to understand the reasoning as to why.

Thank you for your efforts on this important review. This ends our comments.

We would be pleased to answer any questions the Committee may have.