

December 17, 2014

Public statement from Wade Foster, 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 Wade Foster, Manager of Regulatory and Scientific Affairs with The Fertilizer Institute (TFI) and I am pleased to provide the following remarks today. TFI appreciates the time and effort the Chemical Assessment Advisory Committee has put into your review of the draft IRIS Ammonia Assessment. TFI feels the draft report is extremely thorough and generally consistent with the recommendations of both the NRC 2014 and IOM 2011 recommendations for systematic review.

TFI appreciates the attention given to the charge question that asks about the preamble. In its review of the preamble, the CAAC recognized that the preamble describes the general approach and methods that will eventually be used by the IRIS program for all assessments. The CAAC also recognized that the extent to which the preamble methods and approaches were applied in the Ammonia assessment is not clear. Therefore, TFI asks that the preamble include a clear statement noting that it is not specific to the Ammonia assessment and does not represent the methods and approaches that were followed as EPA developed this specific assessment.

TFI agrees with the CAAC that the approach for deriving the RfC is reasonable and clearly described. TFI also strongly agrees with the CAAC recommendation that EPA should attempt to obtain individual-level data and/or the mean/median exposure concentrations for the high dose group from Dr. Holness in order to determine if an alternative point of departure (POD) could be identified, overcoming the limitation of having only the upper exposure range in the published manuscript.

TFI also agrees with the CAAC that, if individual data are unavailable, EPA should consider whether there is sufficient information available in the Holness publication to estimate the mean concentration for the high exposure group--perhaps assuming a lognormal or other skewed distribution for the measured concentrations.

TFI requests that the CAAC recommend that EPA make publicly available any data from the Holness study, as well as rationale and derivation methodology used, for any alternative POD delineated by EPA.

Again, the report contains many excellent observations and recommendations that will help bring the IRIS program closer to implementing the NRC recommendations. TFI looks forward to working with the EPA to derive the most appropriate POD for determining a scientifically sound and protective Reference Concentration for the final IRIS Ammonia Assessment.

We thank the CAAC for their thoughtful deliberation on this important issue. I would be happy to answer any questions.