

### *IRIS STEP 3 INTERAGENCY COMMENTS*

## **OMB Staff Working Comments on EPA's Toxicological Review of Urea [dated June, 2010] and Draft Charge to External Reviewers**

June 28, 2010

### **General Science Comments:**

- The outcome of EPA's review is that the data are not sufficient for the development of an RfC, not sufficient for the development of an RfD and inadequate for a determination of carcinogenic potential. It is our understanding that it is now IRIS policy to send all draft IRIS profiles to contractor-led external peer review panels, or more robust peer review mechanisms for review.
  - It is unclear to us why EPA would allocate appropriated funds for even a contractor-led external peer review panel for the review of a document that essentially makes findings of inadequate data. To save resources (as well as staff and interagency reviewers time), perhaps getting agreement from EPA internal reviewers could be sufficient for such a determination. If EPA felt some type of external review was needed, perhaps EPA could easily reach out to some members of the BOSC to get their endorsement of the findings. This could be done through a quick letter review, rather than paying contractors and other external reviewers for participation in a public meeting.
  - To inform future determinations such as this one, it would be most helpful to the public, internal agency reviewers, interagency reviewers, and expert reviewers, if EPA could provide basic criteria describing the minimum data set that would be needed for RfD/RfC and cancer quantification. The development of such criteria should ideally include opportunity for public input and comment. If EPA could put together even a rough sketch of what this would look like, if EPA continues forward with the review of urea, EPA could use the opportunity to get public, interagency and expert input regarding these criteria. These criteria could then be applied in the future and might streamline the resources and staff efforts put towards creating a toxicological review which makes only a finding of insufficient data.
  - If EPA were to spend the resources to empanel experts, EPA should at least consider asking the experts what future studies should be undertaken to address the data gaps.