TSCA: Two years in

Moderators: Ari Lewis and Karin Baron

Discussion Questions

1. What changes have you noticed in the PMN or LVE process, if any?
    a. Have you been requested to provide additional information? If so, what are the nature of the requests?
    b. Anyone have thoughts about data generated under REACH or another regulatory program that may have data sharing restrictions?
    c. Perform additional testing?
    d. Are you experiencing delays? Have you delayed submitting and LVE/PMN or chosen to substitute an existing chemical to avoid the new chemicals process entirely?

    Responses to the series above:

    - Challenges/difficulties for submitting PMN's
    - Timelines are grossly off and predicting communications within organizations is difficult
    - Assumptions from EPA are worst case
    - Process involves business teams developing a strong argument to continue

2. Have people had any experience with conducting additional testing for a PMN? How does that process work? Has EPA changed how it determines conditions of use, or are PMN submitters providing different types of information about chemical uses and exposures?

    Responses:

    - Until recently, almost every PMN has resulted in additional testing or SNUR
    - Respiratory protection and specific recommendations for protective equipment that may or may not conflict with other agencies (i.e., OSHA)

3. How much thought have people been giving to the existing chemical assessments that have already been announced and have already started to be released? Have you participated in the process in any way (providing data, conditions of use, reviewing the scoping documents or draft assessment for PV29)?

    Response:

- ❖ Discussion on use of REACH robust study summaries for the assessment and the validity of that approach.

4. How about the next round to existing chemical assessments – how are you preparing?

   Responses:

   - ❖ Submitting information can prove to be valuable for companies as was the case with uses for methylene chloride and companies experiences in safely handling these substances
   - ❖ Discussion on how EPA may not include specific use sectors, but then States are banning
   - ❖ If substance of interest is nominated, discussion on the value of getting involved
   - ❖ Discussion on public perception and agency determination

5. Has anyone thought of asking EPA to initiate an assessment? Has TSCA reform changed how readily you turn to new approach methods (NAMS) instead of animal toxicity tests?
6. There was initially a lot of concern about CBI substantiation and possible publication of previously CBI data. Is that still a concern? How are you adapting?

   Response:

   - ❖ Not much discussion of these points. Most agreed that until EPA reviews the CBI claim it is difficult to determine if the claim was adequately substantiated