

## **EDF/Denison oral comments at EPA 12-6-17 new chemicals program public meeting**

Before the Lautenberg Act, the new chemicals program was virtually a black box and was essentially run on a bilateral basis between EPA and industry – with little accountability or opportunity for public engagement.

A number of features served to undermine public confidence in the robustness of EPA reviews and the safety of new chemicals once they entered commerce.

- Because the great majority of new chemical notices include no health and environmental data, EPA had to rely on estimation approaches, with little ability to know the level of uncertainty this entailed. And for many health endpoints of greatest concern, reliable estimation methods simply don't exist.
- Absent information sufficient to establish a new chemical “may present an unreasonable risk,” EPA simply “dropped” the chemical from further review.
- The result? EPA only rarely attached any conditions on new chemicals, and even more rarely required any testing.
- Once added to the TSCA Inventory, the vast majority of new chemicals could be made and used in any manner without informing EPA. Yet companies acknowledge they have limited control over or even knowledge of how their own chemicals are used.

The Lautenberg Act's reforms were intended to address these serious, systemic problems:

- If EPA lacks sufficient information on a new chemical, it must issue an order restricting the chemical to mitigate any unreasonable risk.
- EPA must evaluate potential risks, and mitigate potential unreasonable risks, of a new chemical under its “conditions of use,” which includes “reasonably foreseen” uses as well as those intended by the company notifying EPA.

Sadly, EPA's recent changes actively undercut these key reforms and threaten to cut the public out entirely and turn the program into essentially a service operation for the chemical industry.

- EPA appears to be working to avoid at all costs issuing orders on new chemicals. This means:
  - it cannot require testing;
  - by deferring any evaluation of reasonably foreseen uses to a later separate evaluation, EPA is undermining Congress' intent that EPA reviews reflect that new chemicals may very well be produced and used in ways beyond those initially intended by the submitter of a PMN; and

- once EPA has declared a new chemical “not likely to present an unreasonable risk” and allowed commencement, its only option for addressing risks is through the far slower and more constrained section 6 process.
- Based on what we have gleaned from press reports, companies, EPA staff, agency and industry webinars, etc., EPA’s day-to-day practices appear to have skewed far in industry’s direction:
  - EPA used to argue it was not its role to serve as a coach or consultant to companies to help them “fix” problematic PMNs. Now it is routinely doing so, working with companies to iterate their PMNs in order to be able to make “not likely” findings limited to the companies’ now-revised intended uses.
  - For companies that were initially to be subject to an order, we understand EPA is now offering the alternative of a SNUR-only approach. That is, companies get to decide whether, and if so, how, their new chemicals will be regulated.
  - Where orders in progress required testing, companies have successfully argued for removal of that requirement by noting that the SNUR-only route would not require it.
  - Despite claiming a commitment to greater transparency, EPA has shared numerous written documents with industry to the exclusion of other stakeholders.
    - These include:
      - five so-called “category documents” relating to lung toxicity concerns, and
      - drafts of the “points to consider” document.
    - EPA has solicited and received industry comments on these documents and apparently revised them, without making public those comments or the changes made based on them.
  - EPA has recently slowed or ceased updating its online PMN status database (which has existed for many years), depriving the public of its only reasonable means to discern what interim and final decisions the agency is making on new chemicals.
- Through these actions, many clearly contrary to the law, EPA is returning the new chemicals program to its dark ages under the old TSCA, making it again into a black box within which EPA acts as if its only stakeholder is the chemical industry.