EDF/Denison oral comments at EPA 12-11-17 public meeting on identifying candidates for prioritization

1. In identifying candidates for low-priority designations, EPA needs to acknowledge that the law sets a higher evidentiary bar for such designations relative to high-priority designations.

- First, the law specifies that low-priority designations must be based on *sufficient information* to demonstrate the substance is not high-priority. In contrast, high-priority designations are based on a "*may* present" standard that requires evidence only of "a *potential* hazard and a *potential* route of exposure." Hence more extensive and certain information is needed for a low-priority designation, and EPA should select candidates accordingly.
- Second, low-priority candidates should generally be those that are very unlikely to be high-priority, i.e., they exhibit both low hazard and low exposure potential. Otherwise EPA runs the risk of such candidates, upon further examination, being found to be high-priority – which would bump up the minimum number of chemicals requiring risk evaluations at any given time.
- Third, TSCA makes clear that only chemicals EPA can demonstrate are low-priority across all of their conditions of use can be so designated. This needs to carry over into identifying candidates for low-priority designations: EPA should only put forth chemicals for which it has or will have enough information on their full range of conditions of use to find all of those conditions of use are low-priority.

2. EPA should identify only small numbers of chemicals as candidates for low-priority, especially initially.

- **Building trust, coupled with a lack of experience in making low-priority designations, demands that EPA go slow.** Neither EPA nor the public has experience with the processes leading up to and including prioritization, so EPA should adopt a go-slow approach to identifying candidates for low-priority substances that ensures EPA has sufficient time to focus on each candidate and the public has ample opportunity to comment on each.
    - EPA has stated that it "should strive to identify more than the statutory-mandated minimum of 20 low-priority chemicals." We urge EPA not to make low-priority designations at a pace that significantly exceeds that for high-priority ones.
    - The statute anticipates an approximate balance in the pace at which high- and low-priority designations are made.
    - If EPA designates significant numbers of low-priority chemicals in a short time frame, it will undermine the ability of public interest stakeholders to meaningfully provide comments and have confidence in the process. There must be limits placed on the number of low-priority designations undergoing public comment at any given time, and hence EPA should also be identifying relatively few low-priority candidates at a time.

- Identifying significant numbers of such candidates increases EPA's risk that some of these will be designated high-priority, thereby bumping up the high-priority/ongoing risk evaluation baseline.
- Because low-priority designations are subject to judicial challenge, EPA would also increase that risk if it does not follow a go-slow approach.

3. EPA should not identify categories of chemicals as candidates for low-priority, especially initially.

- In comments on the prioritization rule, industry groups proposed that EPA designate whole lists of chemicals as low-priority that are highly troubling:
    - All chemicals listed as "generally recognized as safe," a designation made with little or no actual independent review
    - All new chemicals or those with SNURs
    - All inactive or low-volume substances

  EPA should avoid this approach at all costs if it is to reflect best available science and build public trust.
- Category members may in fact have very different characteristics, and EPA needs to have sufficient information on *each* chemical it designates as a low priority.
- EPA has proposed to look at chemicals based on use or function categories. But such categories by definition don't encompass all conditions of use. We don't see how this approach would work and comport with the law.
- One example of real concern is chemical intermediates:
    - It cannot be assumed that intermediates invariably result in low exposure;
    - many intermediates have other uses;
    - they may be present as residuals in final products; and
    - these characteristics can be highly variable, differing among batches or producers.

4. In identifying candidates for prioritization, EPA should consider whether at least a minimum set of hazard data should be available or could be quickly developed. This is especially important for low-priority candidates, given the law's information sufficiency requirement.

While EPA cannot require the up-front development of a minimum information set for prioritization purposes [section 4(a)(2)(B)(ii)], nothing in the statute prohibits EPA from specifying the minimum amount of information sufficient to designate a chemical as low-priority.

One starting point might be the OECD Screening Information Dataset (SIDS). The SIDS was developed as the minimum information necessary to conduct a screening-level risk assessment, and is well short of what would be needed to inform a full risk evaluation under the new law.