

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

Good afternoon. My name is Lindsay McCormick, I'm a Project Manager with the Health Program at Environmental Defense Fund.

Due to tight statutory deadlines, it is *critical* that EPA fully utilize its TSCA authorities to collect and generate information and employ strategies to ensure that such information is of high quality before initiating prioritization. Today I will be touching on four points:

- 1) Need to act early to fill information gaps;
- 2) Concerns with over-reliance on voluntary information submissions;
- 3) Need to avoid bias toward information-rich chemicals; and
- 4) Requirements for information transparency.

Need to act early to fill information gaps:

EPA's proposed approaches rely heavily on estimation and modeling as well as high-throughput methods. While these approaches have their place, given their significant limitations, their availability should not be an excuse to avoid acquiring experimental and monitoring data that are needed to conduct a robust risk evaluation and meet the law's "best available science" requirements. For example, robust methods to predict most chronic mammalian endpoints (e.g., developmental toxicity, reproductive toxicity, and immunotoxicity) are lacking. In order to be prepared to adequately assess the risks posed by high-priority chemicals for these endpoints, EPA may need to mandate testing early in the process. Because the gold-standard studies for these endpoints take several years to conduct, in such cases, EPA needs to mandate testing before prioritization begins – in order to meet aggressive statutory deadlines.

Over-reliance on voluntary information submissions

As my colleague, Rob Stockman, previously discussed, EDF urges EPA to use its section 4, 8, and 11(c) authorities to obtain and generate information early in the process and on a routine basis – rather than waiting to see what voluntary information is submitted.

EDF has several concerns regarding EPA's apparent intent to rely heavily on voluntary information submissions:

- A voluntary call is much less likely to produce all of the necessary information than rules mandating its submission. A case in point is EPA’s voluntary reporting Nanoscale Materials Stewardship Program (NMSP), which yielded little information. EPA has provided no empirical evidence establishing that a voluntary approach will result in EPA obtaining all “reasonably available” information.
- EPA has not identified any means to ensure that voluntary submissions are complete and accurate. Companies have a vested interest in EPA finding that their chemicals are not high-priority. Reliance on voluntary submissions may enable companies to omit information they view as raising concerns about their chemicals – that is, “cherry pick” the information.

To the extent that EPA accepts voluntarily submitted information, it should take additional steps to ensure completeness, accuracy, and access to all underlying data.

Avoiding a bias toward information-rich chemicals

EDF recognizes that in the short-term, EPA will identify candidates for prioritization that already have a significant amount of information available (such as Work Plan chemicals). This is both reasonable and supported by provisions of the law, e.g., section 6(b)(2)(B). However, EDF is concerned about establishing a process intended to work over time that introduces an indefinite bias towards information-rich chemicals. EPA should aggressively use its mandatory authorities to obtain information on chemicals, *especially* where little information exists.

Transparency of information:

Health and safety studies and their underlying information are not eligible for CBI protection from disclosure under TSCA. The public – in addition to EPA – needs access to full studies used to identify candidates for prioritization, not simply robust study summaries. Without such access, the public will be unable to meaningfully comment on EPA decisions to include or exclude a study or whether the agency has used the best available science and a weight of the scientific evidence approach.