

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

EPA proposes to adopt an approach to new chemicals review that violates the statutory text and structure of section 5 as amended by the Lautenberg Act.<sup>1</sup> Today, I will briefly discuss some of the legal problems with that approach. I will end by touching on two other areas where the current program is already legally deficient, which EDF urges EPA to address proactively.

**TSCA does not allow EPA to avoid issuing a section 5(e) order for a new chemical substance based on a SNUR; if a chemical substance may present a risk or if EPA has insufficient information on the substance, the plain text of TSCA requires that EPA issue a section 5(e) order.**

1. The text and structure of section 5's new chemical review process is built around the analysis of chemical substances as a whole. TSCA section 5(a)(3) requires EPA to make determinations about each "relevant [new] chemical substance" as distinct from determinations about a "significant new use." Nothing in the language governing new chemicals allows EPA to analyze only some uses of the chemical.
2. TSCA sections 5(a)(1)(A)(i) and 5(d) require any person who wants to manufacture a "new chemical substance" to provide information on that "substance." These provisions do not allow a person to submit a notice limited only to certain "uses" or "intended uses" of a new chemical substance.
3. EPA then must make a section 5(a)(3) determination on the "relevant chemical substance." Nothing in the language allows EPA to limit its review and determination for a new substance based on whether or not a SNUR has been or will be issued.
  - a. If EPA makes one of the section 5(a)(3)(B) findings on that "substance," then EPA must issue a section 5(e) order "to prohibit or limit" the uses of such substance to the extent necessary to protect against an unreasonable risk. Nothing in sections 5(a)(3) or 5(e) authorizes EPA to rely on a SNUR to avoid analyzing the substance under all of its conditions of use or to avoid issuing the mandatory "order." In addition, nothing in these provisions allows EPA to limit its review or determination to intended uses.
  - b. Under TSCA section 5(a)(3)(C), EPA is to make a "not likely to present an unreasonable risk" finding on the "chemical substance" "under the conditions of use." "Conditions of use" is

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<sup>1</sup> EPA's "New Chemicals Decision-Making Framework" suggests that EPA will address concerns about reasonably foreseen conditions of use solely with Significant New Use Rules (SNURs) and that EPA will make a "not likely to present an unreasonable risk" finding based solely on the submitter's intended uses as identified in the final PMN. But this approach is contrary to the statutory text. Indeed EPA has failed to articulate any theory for interpreting the statute to allow this approach.

defined to include the circumstances “under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” Whether or not a SNUR is contemplated or promulgated, it cannot change the requirement for EPA to consider all of those uses in its review of the PMN – including because a SNUR does not permanently foreclose any uses (*i.e.*, they remain reasonably foreseen). And of course, if a SNUR is not legally in-place and in-force at the time EPA makes a decision on the substance, EPA cannot rationally give it any weight under any theory. Among other things, it would be arbitrary and capricious to consider speculative future SNURs that have not been promulgated through rulemaking and do not yet have legal effect.

4. TSCA section 5(f)(4) establishes that a section 5(e) order should generally lead to a SNUR. Thus, using a SNUR to avoid a section 5(e) order completely inverts the relationship Congress expressly created between the two. Congress intended for 5(e) orders: (1) to come first and (2) to trigger SNURs identifying as a significant new use any use that does not conform to the restrictions imposed by the 5(e) order. EPA’s proposed approach—using a SNUR to avoid issuing an order—impermissibly rejects the congressional scheme.

**Rather than adopt a new, illegal approach, EPA should focus its efforts on bringing greater compliance and transparency to the rest of program.**

1. Under TSCA section 5(d), each PMN “shall be made available, subject to section 14, for examination by interested persons,” and under EPA’s regulations, the public file for each PMN should be electronically available. 40 C.F.R. §§ 720.95, 700.17(b)(1). Despite those requirements, PMNs and their public files generally are not available online. EPA should take steps to comply with these regulatory requirements and to ensure that the new chemicals program is transparent to the public.
2. EPA’s issuance to date of the “statement of Administrator findings” required under TSCA section 5(g) for each “not likely” determination is not adequate in light of the law’s requirement that such findings comply with “best available science,” particularly given the definition of “best available science” that EPA has now codified in its regulations. 40 C.F.R. § 702.33. I’ve read every “not likely” finding made since July, and they are largely boilerplate and cursory summaries that do not suffice. EPA needs to start releasing more detailed findings or, at a minimum, the underlying documents that provide the actual basis for these findings (*e.g.*, hazard and exposure/release analyses).