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ENVIRONMENTAL DEFENSE FUND
Finding the ways that work

August 16, 2017

Jeffery Morris
Director, Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
1200 Pennsylvania Ave., NW
Washington, DC 20460

Dear Jeff:

Attached please find a list of questions regarding EPA's new chemical reviews under TSCA. We are requesting that you provide written answers to these questions as soon as reasonably possible.

As a key stakeholder in implementation of the Lautenberg Act's changes to section 5 of TSCA, and in light of recent announcements by the agency regarding significant changes that have been or will be made to new chemicals reviews under TSCA, EDF believes that having timely answers from the agency to these questions is critical.

We recognize that some of these questions may be more quickly answered than others; if that is the case, we would ask that you provide us with answers to the questions as you can and not wait until all questions have been answered to respond back to us.

Please don't hesitate to let us know if the questions are not clear, you need more information, or wish to discuss this with us.

Sincerely,

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Questions for EPA:

New policies

1. An August 7, 2017, EPA news release briefly describes new "operating principles" that are to govern new chemical reviews. Few details are provided, however. Will the new policies and practices be fully explained to the public by EPA, and the legal and scientific justifications for them be provided? If so, when?
2. Are these new policies and practices in effect? If so, when did they commence and why are they being implemented before any opportunity for the public to learn about them and provide comments? If not, when will they be implemented, and will the public be afforded an opportunity to comment beforehand?

Non-5(e) SNURs

3. One of the new policies indicates EPA will rely on so-called non-5(e) SNURs in lieu of consent orders in certain cases. What are the specific circumstances where this approach will be applied? Will the cases where this has been done be clearly identified to the public? If not, why not? If so, how will they be clearly identified?
4. The policy appears to suggest that EPA will rely on the non-5(e) SNUR to make a "not likely to present an unreasonable risk" finding for the chemical substance that is the subject of the PMN. Is this the case? If so, will the "not likely" finding statements detail specifically what aspects and conditions of the PMN are the basis for the finding, and not just in general terms?
5. Will the associated non-5(e) SNURs specify in detail what constitute significant new uses (SNUs), with specific reference to the originating PMN and identifying any allowed deviation from the specifications in the PMN? For example, if the PMN delineates the specific type or level of protection of any respirator to be used by workers, will the SNUR specify the same type or level of protection of respirator, and not simply identify as a SNU the failure to use any type of respirator?
6. Will SNUN reviews consider the multiple combined exposures arising from both the new and prior (PMN-associated) conditions of use? Will the SNUR account for the combined potential effect on risk of the activities of multiple companies, each of which is complying with the terms of the SNUR? If so, how? For example, each company may comply with a volume limit but the aggregate volume could be of concern if multiple companies are making a SNUR'd chemical.
7. What legal guarantee will there be that final SNURs will be in place before "not likely" findings are made?
8. What will happen in the event of a judicial challenge of a final SNUR with respect to the associated new chemical? Will EPA wait until the window for challenging a final SNUR has closed to issue any "not likely" determination? If a challenge is filed, will EPA wait until that challenge has been fully resolved and a final SNUR is in fact in place (assuming EPA prevails) to issue any "not likely" determination? What happens if a SNUR is invalidated by a court?

Related policy decisions

9. Based on the August 7 news release and other sources, EPA appears to have made a number of other policy decision regarding new chemicals, e.g., basing "not likely" findings on application of a polymer flag to the Inventory listing; changes or clarifications to LVE/LoREx exemption request decisions; limiting testing only to cases where it is needed "to address risk concerns."
    a. Will the details of these new policies be publicly announced and the legal and scientific justification for them be provided, and if so, when?
    b. Have these policies already been shared with PMN submitters or other industry interests? If they have been shared with parties outside of EPA, why have they not been shared with the broader public? Will EPA now share them?
10. Press reports point to EPA having developed and shared with some industry interests new "category documents" relating to new chemical reviews.
    a. Are these category documents publicly available? Are there other related documents EPA has developed explaining the context for them? If so, where and how can all these documents be accessed? If they cannot be accessed, why not?
    b. With whom have these documents been shared? The press reports suggest that EPA has also received comments from some industry interests on these documents. Did EPA solicit comments from those with whom they were shared? Why was this opportunity not provided to others?
    c. Are the comments EPA has received publicly available? If so, where and how can they be accessed? If not, why not?

Public access to information

Under TSCA section 26(j)(1), EPA "shall make available to the public—all notices, determinations, findings, rules, consent agreements, and orders of the Administrator under this title."

11. Under TSCA section 5(d), each PMN "shall be made available, subject to section 14, for examination by interested persons." What steps are you taking to make those PMNs available for public examination?
12. Will EPA commit to promptly releasing all PMNs and consent orders for new chemicals reviewed under the new law (redacted as appropriate)?
13. 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 reference to and EPA's definition of "best available science." When does EPA plan to start releasing documents that provide the actual basis (e.g., hazard and exposure/release reports) for these findings, not just the summary now being provided?

CBI, chemical identity, and unique identifier

14. Are all non-exempt CBI claims in PMNs being reviewed in accordance with section 14 requirements?

a. How can the public be assured that this is happening and will continue to happen? How can the public track the results of these reviews?
b. EPA section 14(g) states that the EPA's decisions on CBI claims are "determinations." Thus, they must be disclosed under section 26(j)(1). What plans does EPA have to make these determinations, including associated substantiations, available to the public?

15. For chemical identities (chemIDs) in notices of commencement (NOCs) for which EPA has approved a CBI claim, has EPA assigned unique identifiers, and if so, where and how are they being made available? If not, why not?
16. To provide generic names for chem IDs that are deemed CBI, EPA is still using the "Instructions for Developing Generic Names for Premanufacture Notices (PMNs) in the TSCA Inventory, 1985." The Amendments to TSCA section 14 require that EPA develop guidance for generic names and that the guidance and the new names meet certain requirements. What progress has EPA made on developing that new guidance for generic names?
17. What progress is EPA making on developing the rule establishing the review plan required by TSCA section 8(b)(4)(C)? EPA is going to need to issue a final rule on the review plan within one year of the "the date on which the Administrator compiles the initial list of active substances."

5(e) SNURs

18. TSCA § 5(f)(4) directs that, after EPA issues an order under § 5(e), EPA must within 90 days consider whether to promulgate a SNUR and either "initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking."
    a. A significant number of consent orders EPA has finalized were issued well over 90 days ago. It does not appear, however, that EPA has to date taken either of the actions specified under TSCA § 5(f)(4). Has EPA taken such actions, and if so, why are they not visible to the public? If not, why not?
19. Prepublication versions of Federal Register notices posted on EPA's website indicate EPA issued final SNURs for 37 substances on April 5, 2017, and for another 29 substances on July 7, 2017, both as direct final rules. However, these SNURs have not in fact been finalized, as they have never been published in the Federal Register.
    b. Why have these rules not been finalized months after the rules were signed and sent to OFR for publication?
    c. In light of EPA's stated intent to rely heavily on SNURs in its new chemical reviews going forward, what are the implications of these substantial delays in finalizing SNURs for ensuring timely action?