Environmental Defense Fund Questions for

Public Meeting on Implementing Changes to the New Chemicals Review Program

under Amended TSCA

Docket ID: EPA-HQ-OPPT-2017-0585

Submitted Monday, November 20, 2017

Environmental Defense Fund (EDF) appreciates the opportunity to provide questions for the Environmental Protection Agency (EPA) to address during the December 6, 2017, public meeting on the implementation of changes to the new chemicals review program under amended TSCA. EDF looks forward to hearing EPA's responses to these questions at the meeting.

New policies

1. An August 7, 2017, EPA news release briefly describes new "operating principles" that are to govern new chemical reviews, and EPA has now provided a short "framework" for review. Few details are provided, however. When and how will the new policies and practices be fully explained in writing by EPA, including the legal and scientific justifications for them?
2. Does EPA intend to further elaborate on the general criteria that are laid out in the framework (e.g., through additional guidance or other means)?
3. The framework fails to address several core issues related to testing; will EPA address them in the future? For example, the framework provides no specificity as to EPA's use of its enhanced information generation authority under the law, including section 4, which expressly extends to the review of notices under section 5 of TSCA.[1]
    a. Under what circumstances will EPA use its authority to require information development by submitters of new chemical notices?
    b. In the operating principles articulated in its August news release, EPA appears to have re-created the infamous Catch-22 of old TSCA under which EPA could only require testing where it already had evidence of risk. In the release, EPA indicates that testing is to be required only "to address risk concerns," and the release fails to acknowledge its authority to address cases where there is insufficient information. The analogous language in the framework appears to have been improved and made more consistent with the law. Does the framework language now supplant the press release, and if so, when will EPA update and clarify its operating principles it included in the news release?

[1] The framework refers to testing in only one bullet, appearing on page 3: "The purpose of testing in a section 5 order is to reduce uncertainty in making risk determinations. Specifically, it is generally to reduce uncertainty associated with assessments that gave rise to a finding of 'may present unreasonable risk' or to an 'insufficient information' determination."

c. The framework only refers to testing in the context of issuing a section 5 order, but much of the framework seems designed to evade issuing section 5(e) orders and instead to rely on non-5(e) SNURs. One significant concern with that approach is that EPA can mandate testing to address insufficient information with a section 5(e) order, but SNURs do not provide this direct authority to require testing. Why is this substantial difference not mentioned in the framework, and how does EPA intend to address it? How will EPA address insufficient information with a SNUR?
d. Why does the framework ignore EPA's authorities under section 4 to require the development of new information as necessary for the review of section 5 notices?

4. Based on the August 7 news release, EPA indicates it will interpret the term "reasonably foreseen" to mean "probable" in identifying and evaluating potential conditions of use of a PMN substance. What is the statutory basis for this interpretation?
5. These new policies and practices appear already to be in effect. If so, when did they commence and why were they implemented before any opportunity was provided for the public to learn about them and provide comments?

Non-5(e) SNURs

6. One of the new policies indicates that EPA will rely on so-called non-5(e) SNURs in lieu of consent orders at least in some cases.
    a. Why does EPA believe this approach is preferable to the more straightforward reading of the law and EPA's practice since the passage of the Lautenberg Act? Does EPA consider it more health-protective?
    b. What are the specific circumstances where this approach will and will not be applied?
    c. Will the cases where this is done be clearly identified to the public? If not, why not? If so, how and when will they be clearly identified?
7. The policy suggests that EPA will rely on the non-5(e) SNUR in order to make a "not likely to present an unreasonable risk" finding for a PMN substance. Is this the case? If so, will the accompanying "not likely" finding statement describe in detail specifically what aspects and conditions of the PMN are the basis for the finding, and not just in general terms?
8. EPA can only make a section 5(a)(3)(C) "not likely to present an unreasonable risk" finding for a new "chemical substance" based on the substance *as a whole* and under its "conditions of use," which includes intended, known, or reasonably foreseen conditions of use. Section 5(g) requires EPA to make a public statement articulating any finding – which must be made "in accordance with subsection (a)(3)(C)" – that "*a chemical substance* *** is not likely to present an unreasonable risk of injury to health or the environment." What legal basis does EPA have for considering the existence of a SNUR in making that finding or for limiting the scope of its analysis of the new substance based on the SNUR?
9. Will the associated non-5(e) SNURs specify in detail what constitute significant new uses (SNUs) of the PMN substance, with specific reference to the originating PMN and clearly 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? If not, why not?

10. Will SNUN reviews consider the multiple combined exposures arising from both the new and prior (PMN-associated) conditions of use? How will reasonably foreseen uses associated with the SNUN review be addressed?
11. Will the SNUR account for the potential combined 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 start to make or use a SNUR'd chemical.
12. Where EPA intends to use a non-5(e) SNUR to address concerns about reasonably foreseen uses of a PMN substance, coupled with a "not likely" finding issued to the PMN submitter, will EPA ensure the SNUR is in place prior to issuing the finding or allowing commencement of the manufacture of the PMN substance? If not, why not? If so, how? What legal guarantee will there be that final SNURs will be fully and permanently in place before "not likely" findings are made?
    a. If EPA promulgates a SNUR through a direct final rule, what will happen in the event an adverse comment, or an indication of intent to submit an adverse comment, is filed? Will EPA wait until the SNUR is proposed and finalized to issue any "not likely" determination?
    b. What will happen in the event of a judicial challenge of a final SNUR with respect to the associated PMN substance? 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

13. Based on the August 7 news release and other sources, EPA appears to have made a number of other policy decisions regarding new chemicals, e.g., basing "not likely" findings on application of a polymer flag to the Inventory listing, and changes or clarifications to LVE/LoREx exemption request decisions.
    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 publicly share them?
14. 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? If not, why not?
    b. Are the category documents currently being used to inform EPA new chemical reviews?

c. Are there other related documents EPA has developed explaining the context for the category documents and their use in new chemical reviews? If so, where and how can all these documents be accessed? If they cannot be accessed, why not?
d. With whom have these category documents and any related documents been shared? The press reports suggest that EPA has also received comments from some industry interests on the category documents. Did EPA solicit comments from those with whom they were shared? Why was this opportunity not provided to others?
e. Are the comments EPA has received publicly available? If so, where and how can they be accessed? If not, why not?
f. When is EPA planning to release these documents, including drafts shared with and comments received from industry?

15. EPA provides an "Overview of Comments Received on the Draft 'Points to Consider' Document," which makes clear it provided the draft to some parties for their review and comment. But EPA never provided stakeholders generally with an opportunity to comment on that document.
    a. Who did EPA solicit comments from and by what mechanism? Are the comments EPA has received publicly available? If so, where and how can they be accessed? If not, why not?
    b. Why was this opportunity provided to some stakeholders but not others?
    c. Does the draft now being provided to the public include changes made in response to comments EPA received on the initial draft? If so, why isn't EPA also making available the initial draft so that the changes it made in response to those selective stakeholders can be discerned?

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."

16. Under TSCA section 5(d), each PMN "shall be made available, subject to section 14, for examination by interested persons." What steps is EPA taking to make those PMNs available for public examination, as required by law?
    a. EPA's regulations provide that "[a]ll information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the public file for that notice, unless such materials are claimed confidential." 40 C.F.R. § 720.95. Those "[p]ublicly available docket materials are available at the addresses in § 700.17(b)(1)." 40 C.F.R. § 720.95. Section 700.17(b)(1) states that "[p]ublicly available docket materials are available in the electronic docket at http://www.regulations.gov." 40 C.F.R. § 700.17(b)(1). Despite these regulatory obligations, EPA is not creating the publicly available electronic dockets.
    b. EPA's regulations already require that PMN submitters, if they claim information in either the PMN or attachments is confidential, "must also provide EPA with a sanitized copy." 40 C.F.R. §§ 720.40(d)(2), 720.80(b)(2). Indeed, "the notice review period will

not begin until EPA receives the sanitized copy." 40 C.F.R. §§ 720.80(b)(2)(iii), 720.65(b)(vii) ("[T]he notification period does not begin if *** the submitter does not submit a second copy of the submission with all confidential information deleted for the public file."). "EPA will place [the] sanitized copy in the public file." 40 C.F.R. § 720.80(b)(2)(ii). Therefore, EPA should not begin reviewing PMNs until it has received sanitized copies of the PMN and attachments for public release, and EPA should place those sanitized public copies in the electronic docket as soon as the review begins.

c. Will EPA commit to promptly making publicly available electronic dockets containing all PMNs, supporting documentation, and the results of EPA's PMN reviews, as well as all consent orders for new chemicals reviewed under the new law (with the only information redacted from these documents being that allowed pursuant to confidentiality claims asserted and permitted under TSCA section 14)?

17. 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?
18. More than two months ago, EPA stopped updating its PMN status database/table on its website. This means of tracking PMN status has been available for many years or decades. Why has EPA stopped updating it, when it continues to make decisions about new chemicals as evidenced by its weekly updating of the new chemical review statistics on another page of its website?

CBI, chemical identity, and unique identifier

19. Are non-exempt CBI claims in PMNs and supporting documentation 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 and ensure they are being conducted in a timely manner as required by law?
    b. TSCA section 14(g) states that the EPA's decisions on CBI claims are "determinations." Thus, they must be disclosed under TSCA section 26(j)(1). What plans does EPA have to make these determinations, including associated substantiations, available to the public? When will this be done?
20. For chemical identities (chemIDs) in notices of commencement (NOCs) for which EPA has approved a CBI claim, has EPA assigned unique identifiers, as required under TSCA section 14(g)(4)? If so, where and how are they being made available? If not, why not and when will EPA do so?
21. 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?

22. 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

23. TSCA section 5(f)(4) directs that, after EPA issues an order under section 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 after the date of enactment of the Lautenberg Act were issued well over 90 days ago. For many of them, however, it does not appear that EPA has to date taken either of the actions specified under TSCA section 5(f)(4).[2] Has EPA taken such actions, and if so, why are they not visible to the public? If not, why not?
24. Prepublication versions of Federal Register notices previously posted on EPA's website indicated that 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 were not finalized for months, finally being published in the Federal Register on September 21, 2017, and October 19, 2017, respectively.
    a. Why were these rules not finalized until months after the rules were signed and sent to OFR for publication?
    b. 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?

[2] EPA has issued SNURs for 29 of these chemicals, though outside the 90-day window for many of them. *See* 82 Fed. Reg. 48,637 (Oct. 19, 2017).