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News Alert

Ten Things PMN Submitters Need to Know

Does your company plan to submit a premanufacture notice (PMN) under section 5 of the Toxic Substances Control Act (TSCA)? Has it done so recently? If so, you need to know the answers to ten key questions:

1. What are the new fees and when will they be assessed?
2. How does EPA interpret the possible PMN determinations?
3. How does EPA interpret "conditions of use"?
4. How often does EPA make each determination?
5. What is the timeline for EPA to make its determination?
6. How can a submitter increase the likelihood of a favorable (or at least faster) determination?
7. What is EPA likely to include in a section 5(e) order?
8. How likely is EPA to adopt a significant new use rule (SNUR) for a PMN substance?
9. What is the timeline for EPA to adopt a SNUR following a section 5(e) order?
10. What are the prospects for a "not likely" determination and a non-order SNUR?

This alert provides answers to those questions based on what EPA has said and done since enactment of the TSCA amendments on June 22, 2016 by the Frank A. Lautenberg Chemical Safety for the 21st Century Act (LCSA), Pub. L. 114-182 (June 22, 2016).

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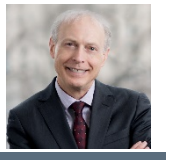

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What Are the New Fees and When Will They Be Assessed?

Under EPA's new fees rule, the fee for a PMN is $16,000, an increase from the former fee of $2,500. For small businesses, the fee is $2,800.

The final fees rule, 40 C.F.R. Part 700, applies to all PMNs received starting on October 1, 2018 and continuing through Sept. 30, 2021. The fees will increase thereafter to adjust for inflation.

How Does EPA Interpret the Possible PMN Determinations?

EPA must make one of five determinations after completing its review of a PMN:

- The PMN substance "presents" an unreasonable risk of injury to health or the environment under the conditions of use.
- The information available to EPA is "insufficient" to permit a reasoned evaluation of the PMN substance.
- In the absence of sufficient information, the PMN substance "may present" an unreasonable risk of injury to health or the environment [under the conditions of use].
- The PMN substance is or will be produced in "substantial quantities" and may reasonably be expected to enter the environment in substantial quantities or there may be significant or substantial human exposure.
- The PMN substance "is not likely to present" an unreasonable risk of injury to health or the environment under the conditions of use.

EPA must make its determinations without consideration of cost or other non-risk factors. It must consider an unreasonable risk of potentially exposed or susceptible subpopulations, such as workers or pregnant women.

EPA has clarified how it interprets those determinations:

- The "presents" determination is similar to the "may present" determination (see below), except that here there is sufficient information that the level of uncertainty in the risk assessment is relatively low. Under this scenario, EPA will issue an order under section 5(f) or a proposed rule under section 6. A section 5(f) order may ban one or more uses of the PMN substance, but it could be limited to requiring exposure controls and possibly testing.
- The "insufficient information" determination means either (1) that EPA lacks key information on the PMN substance or an analog, and thus it cannot make a reasoned evaluation; or (2) that EPA has sufficient hazard information but has no benchmark on exposure to allow it to assess the risk. With this determination, EPA may issue an order under section 5(e) requiring the PMN submitter to conduct testing and submit the test results to EPA prior to commercialization.
- The "may present" determination means that EPA cannot make a "presents" determination due to limited information, but the information available indicates that the PMN substance may present health and/or environmental hazards of concern, and one or more exposure scenarios presents an unreasonable risk. With this finding, EPA will issue a section 5(e) order. If it considers that

exposure controls can adequately manage the risks, it will require the use of exposure controls and may require the PMN submitter to conduct testing after commercialization. Otherwise, it will require the PMN submitter to conduct and submit testing prior to commercialization.

- The "substantial quantities" determination is based on EPA's longstanding exposure-based guidelines (*e.g.*, production greater than 100,000 kg/year). This finding will usually trigger a section 5(e) order with exposure-based testing requirements.
- If EPA makes the "not likely to present" determination, the PMN submitter may begin commercial production immediately, and EPA will issue a statement under section 5(g) explaining its determination. It means either that:
  - EPA has found the PMN substance to have low potential for human and environmental toxicity and the substance is not both persistent and bioaccumulative.
  - Toxicity is higher but all exposure scenarios do not present unreasonable risks.
  - The substance may have the potential for higher toxicity but there is little potential for exposure due to its physical-chemical properties.

How Does EPA Interpret "Conditions of Use"?

For three of the possible determinations – "may present," "presents," and "not likely to present" – EPA must make the determination in light of the PMN substance's "conditions of use." TSCA section 3(4) defines "conditions of use" to mean "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of."

In determining the conditions of use, EPA has said that it uses information in the PMN and in the literature; attributes of the substance (such as its physical-chemical properties); information on analogs of the substance in light of any differences between the substance and the analog; and information on downstream processing and use of the substance and analogs. More specifically, EPA has explained:

- In general, the "intended" uses are those in the PMN.
- "Known" conditions of use include activities within the United States that result from manufacture that is exempt from PMN submission requirements.
- "Reasonably foreseen" conditions of use are future circumstances determined on a highly fact-specific, case-by-case basis. EPA says it will use its professional judgment, experience, and discretion – not hypotheticals or conjecture – when considering such factors as:
  - Evidence of current use of the new chemical substance outside the U.S.
  - Evidence that the PMN substance is sufficiently likely to be used for the same purposes as existing substances that are structurally analogous.
  - Conditions of use identified in an initial PMN submission that the submitter omits in a revised PMN.

With respect to the "reasonably foreseen" criterion, many section 5(e) orders require the use of the exposure controls in the PMN or amended PMN, suggesting that EPA regards the nonuse of those controls – either by the PMN submitter or others – to be "reasonably foreseen" and sufficient to trigger a "may present" determination.

Conceivably, EPA may not have a concern with the conditions of use described in the PMN or amended PMN, but it may have concerns about the conditions of use of potential future manufacturers and processors. In that case, it must determine whether those "reasonably foreseen" uses "may present" an unreasonable risk. In that circumstance, PMN submitters may want to argue that EPA should not make a "may present" determination. EPA's only option after making that determination is to issue a section 5(e) order to the PMN submitter – which will have no effect whatsoever on the potential future manufacturers and processors whose uses are the basis for the concern.

How Often Does EPA Make Each Determination?

By far the most frequent determination is "may present." In the 27 months since enactment of the LCSA (through September 27, 2018), EPA has make 498 final PMN determinations. Of those, EPA made:

- 2 "presents" determinations resulting in a section 5(f) order (0.4%).
- 2 "insufficient information" determinations resulting in a section 5(e) order (0.4%).
- 16 "may present" determinations resulting in a section 5(e) order (for 1 of which EPA also made a "substantial quantities" determination) (83.5%).
- 1 "substantial quantities" determination resulting in a section 5(e) order (for which EPA also made a "may present" determination) (0.2%).
- 78 "not likely to present" determinations resulting in a section 5(g) statement (15.7%).

Thus, all other things being equal, a PMN submitter should expect EPA to make a "may present" determination and issue a section 5(e) order for its PMN substance unless it can convince EPA that "not likely to present" is more appropriate.

What is the Timeline for EPA to Make Its Determination?

Section 5(a) gives EPA 90 days in which to make a determination, subject to an extension under section 5(c) of up to 90 days. EPA rarely makes extensions. Instead, EPA typically asks the submitter to request a suspension of the running of the original 90-day period. If the submitter refuses to suspend the running of the 90-day period, EPA will likely trigger a 90-day extension and proceed to issue a unilateral section 5(e) order, which is likely to be less favorable than a negotiated section 5(e) consent order, which is the typical result. Thus, PMN submitters routinely agree to suspend the timeframe. Cumulative suspensions often mean that the nominal 90-day period runs for a year or longer.

EPA took an average of:

- 344 days from the date of PMN receipt to issue the 2 "presents" determinations (no range).
- 347 days from the date of PMN receipt to issue the 2 "insufficient information" determinations (range of 282 to 412 days).
- 307 days from the date of PMN receipt to issue 198 of the 416 "may present" determinations (range of 113 to 1,561 days).
- 164 days from the date of PMN receipt to issue the "not likely to present" determinations (range of 31 to 1,270 days).

- EPA also reports the dates that review began for PMNs that resulted in "not likely to present" determinations (but has not explained why the date review began is not the date that the PMN was received for PMNs originally received after June 22, 2016). The average was 136 days (range of 28 to 724 days).

How Can a Submitter Increase the Likelihood of a Favorable (or at Least Faster) Determination?

The most favorable determination is a "not likely" determination. The next most favorable determination is a "may present" determination that comes sooner rather than later.

As an initial matter, the PMN submitter should ensure that it meets the technical requirements for submitting a PMN. (The 90-day clock does not begin until EPA considers a PMN to be complete.) Be sure to review carefully the PMN Instruction Manual, the updated "Points to Consider" guidance document, and other helpful EPA guidance before submission. EPA has posted a presentation on common errors that PMN submitters should avoid.

Next, find out what you are up against. Compare the PMN substance against EPA's Chemical Categories. (EPA has informally updated this 2010 document by adding several categories related to lung effects, photo-acid generators, tracer chemicals, and perfluorinated chemicals.) Consider developing hazard data before submission, particularly for substances covered by an EPA Chemical Category. Otherwise, EPA will utilize models and conservative assumptions about toxicity. This data is best developed before submission of the PMN.

Further understanding and potential arguments can come from using the Sustainable Futures Initiative tools. According to EPA, this voluntary program encourages chemical developers to use EPA models and methods to screen new chemicals for potential risks early in the development process. Companies that take training and graduate from Sustainable Futures can earn expedited review by EPA for prescreened new chemical notices.

Similarly, for substances likely to be regarded by EPA as presenting hazards, review carefully controls that would limit exposure (*e.g.*, for aquatic toxicity concerns, ensuring that the substance is not released to water through disposal). Engineering controls are likely to carry greater weight with EPA than personal protective equipment. Build these controls into the original PMN.

Finally, stay in close touch with the PMN manager assigned to your PMN. The PMN staff is overloaded. Asking for status updates and providing requested information promptly can help focus staff attention on your PMN as opposed to the others in the queue.

What Is EPA Likely to Include in a Section 5(e) Order?

Section 5(e) orders may include requirements for testing, worker protection, and hazard communication; and limitations on volume, use, disposal, and distribution.

EPA has posted the boilerplate that forms the basis of most section 5(e) orders. If a PMN submitter would like to avoid a requirement to use respirators, EPA may add a new chemical exposure limit (NCEL) to the order. The boilerplate for NCEL provisions is also on the EPA website.

Actual section 5(e) orders are also available through the table on the status of PMNs. Reviewing section 5(e) orders for chemicals whose chemical names or generic names suggest that they are structurally similar to your PMN substance may be helpful.

How Likely Is EPA to Adopt a SNUR for a PMN Substance?

EPA is likely to adopt a SNUR for a PMN substance for which it has issued a section 5(e) order. If EPA does not issue a section 5(e) order, a SNUR is also possible, as addressed in the final section of this alert.

Section 5(f)(4) directs EPA to "consider whether" to adopt a SNUR for a PMN substance following issuance of a section 5(e) order for that substance "and, as applicable, initiate such a rulemaking" or publish a statement on why it will not adopt a SNUR. These SNURs generally apply key provisions of the corresponding section 5(e) orders.

As noted above, since enactment of the LCSA, EPA has issued section 5(e) orders for 418 PMN substances with effective dates after enactment. So far, it has published direct final SNURs for 352 of those substances (about 84% of the section 5(e) orders issued since enactment). For details, see below. It has published 0 statements saying it will not adopt a SNUR following issuance of a section 5(e) order.

What is the Timeline for EPA to Issue a SNUR Following a Section 5(e) Order?

EPA actions under section 5(f)(4) are due "not later than 90 days after" issuing the section 5(e) order. Arguably, to "initiate such a rulemaking" can mean something short of publishing a rulemaking notice.

EPA typically adopts SNURs for PMN substances through an expedited rulemaking procedure. The procedure for where EPA has issued a section 5(e) order calls for EPA to publish a rulemaking notice within 180 days after receipt of a notice of commencement of manufacture (NOC) of the PMN substance, unless EPA decides not to adopt a SNUR (this regulatory deadline has been effectively superseded by section 5(f)(4)). The procedure for where EPA does not issue a section 5(e) order but does intend to adopt a SNUR calls for EPA to publish a rulemaking notice within 270 days of receipt of an NOC.

Since enactment of the LCSA, EPA has published direct final SNUR rulemaking notices for PMN substances between 7 and 22 months after issuing section 5(e) orders for those substances, with the time gap lessening as EPA works through its backlog. They include:

- **Nov. 17, 2016:** SNURs for 34 PMN substances for which it had issued section 5(e) orders with effective dates ranging from July 1, 2015 to Dec. 21, 2015 (about 11-17 months before the rulemaking).
- **Sept. 21, 2017:** SNURs for 6 PMN substances for which it had issued section 5(e) orders with effective dates ranging from Jan. 15, 2016 to June 21, 2016 (about 14-19 months before the rulemaking).
- **Oct. 19, 2017:** SNURs for 29 PMN substances for which it had issued section 5(e) orders with effective dates ranging from Nov. 2, 2016 to Mar. 7, 2017 (about 7-11 months before the rulemaking).

- **After a 9-month hiatus, Aug. 1, 2018:** SNURs for 145 PMN substances for which it had issued section 5(e) orders with effective dates ranging from Mar. 13, 2017 to Aug. 4, 2017 (about 12-17 months before the rulemaking).
- **Aug. 17, 2018:** SNURs for 27 PMN substances for which it had issued section 5(e) orders with effective dates ranging from May 4, 2017 to June 23, 2017 (about 12-14 months before the rulemaking).
- **Aug. 27, 2018:** SNURs for 10 PMN substances for which it had issued section 5(e) orders with effective dates ranging from Nov. 2, 2016 to Aug. 5, 2017 (about 13-22 months before the rulemaking).
- **Aug. 27, 2018:** SNURs for 19 PMN substances for which it had issued section 5(e) orders with effective dates ranging from June 16, 2017 to July 31, 2017 (about 12-14 months before the rulemaking).
- **Sept. 17, 2018:** SNURs for 28 PMN substances for which it had issued section 5(e) orders with effective dates ranging from Aug. 7, 2017 to Sept. 26, 2017 (about 12-13 months before the rulemaking).
- **Oct. 3, 2018:** SNURs for 26 substances for which it had issued section 5(e) orders with effective dates ranging from May 11, 2017 to Feb. 27, 2018 (about 7-17 months before the rulemaking).
- **Oct. 10, 2018:** SNURs for 28 chemical substances for which it had issued section 5(e) orders with effective dates ranging from Jan. 5, 2018 to Mar. 5, 2018 (about 7-9 months before the rulemaking).

What Are the Prospects for a Non-Order SNUR?

There is no provision corresponding to section 5(f)(4) to mandate that EPA consider adopting a SNUR after (or while) making a "not likely" determination. Nevertheless, EPA may consider making a "not likely to present" determination and adopting a SNUR in appropriate circumstances. It said this in a November 2017 draft New Chemicals Decision-Making Framework. Similar statements appear on the EPA website.

Until recently, however, the only SNURs that EPA had published since the LCSA enactment without previously issuing a section 5(e) order were for PMNs reviewed before enactment (23 SNURs among those published on Nov. 17, 2016 and 31 SNURs among those published on Sept. 21, 2017). For each of those SNURs, the rulemaking notice stated, "EPA has not determined" that the substance "may present an unreasonable risk." EPA had not published a SNUR for any substance following, or in connection with, a "not likely to present" determination.

But in October 2018, that situation changed. On October 9, EPA made "not likely to present" determinations for 13 PMN substances (P-16-0192, -0354 and -0355, -0380 through -0885, -0483 and -0484, -0575, and -0851), finding in each case that "The chemical substance is not likely to present an unreasonable risk … under the conditions of use, based on the risk assessment presented below and the terms of the Significant New Use Rule (SNUR) signed by EPA …." On October 16, EPA published proposed non-order SNURs for those 13 substances.

These are proposed SNURs, not direct final rules. EPA explained in the "not likely" determinations for these substances:

> *Based on EPA's experience, it is the Agency's judgment that a new use would not commence during the pendency of a proposed SNUR because web posting of a proposed*

> *SNUR serves as the cut-off date for a significant new use. Therefore, manufacturers and processors would not commence a prohibited new use that would be legally required to cease upon finalization of the SNUR. Once a SNUR is final and effective, no manufacturer or processor – including the PMN submitter – may undertake the conditions of use identified as a significant new use of the PMN substance in the SNUR ….*
>
> *If EPA were not to finalize the proposed SNUR, then that decision would be based on information and data provided to the Agency during the comment period demonstrating that the reasonably foreseen conditions of use subject to the proposed SNUR are not likely to present an unreasonable risk. Under either scenario, the reasonably foreseen condition of use is not likely to present an unreasonable risk.*

It is unclear at this time whether EPA plans to make similar "not likely to present" determinations and propose SNURs for other PMN substances, but the fact that the Agency has done so once is encouraging for PMN submitters.

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