Comments on

Inventory Reset and CBI Claim Review Rule(s)

Submitted September 16, 2016

EDF appreciates the opportunity to provide the following comments to EPA as input into its development of its Inventory Rule(s) called for under new TSCA section 8(b)(4).

Summary

In developing these rule(s), EDF believes EPA needs to do the following:

- Make clear that no volume or other thresholds and no reporting exemptions apply to its Inventory reset.
- Make clear that only CBI claims for chemicals that are already confidential on the Inventory can be requested to be maintained.
- Make clear that no *new* CBI claims can be asserted and requested to be maintained even for chemicals that are confidential on the Inventory.
- Specify the substantiation and record-keeping requirements applicable to companies' identification of active chemicals.
- Specify a deadline by which it will identify all active and inactive chemicals on the Inventory.
- Specify a deadline by which it will disclose the identities of active chemicals for which it does not receive any requests to maintain confidentiality.
- Specify the timing and content of companies' substantiation of CBI claims they seek to maintain.
- Indicate how it will pace its reviews under the review plan so as to meet the 5-year deadline and minimize the likelihood of needing an extension.
- Integrate claims asserted and reviewed under section 8 into the procedures and systems it develops for chemical identity claims asserted and reviewed pursuant to section 14.
- Specify how it will decide whether or not it is necessary to determine the priority of a newly activated chemical.
- Make clear that the public information requirements of section 8(b)(7) apply to chemical identity claims under both sections 8 and 14.

General comments

Amendments to TSCA section 8(b)(4) made by the Lautenberg Act specify that EPA:

- "by rule, shall require manufacturers, and may require processors ... to notify the Administrator, by not later than 180 days after the date on which the final rule is published in the Federal Register, of each chemical substance on the list published under paragraph (1) [the TSCA Inventory] that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act" *["Inventory reset," section 8(b)(4)(A)(i)]*; and
- "shall promulgate a rule that establishes a plan to review all claims to protect the specific chemical identities of chemical substances on the confidential portion of the list published under paragraph (1) that are asserted pursuant to subparagraph (B)." *["CBI claim review plan," section 8(b)(4)(C)]*

The first rule is to be met within one year of enactment, while the second rule is to be met not later than one year after EPA compiles the initial list of active substances pursuant to the first requirement.

As a preliminary matter, while EPA clearly could promulgate two separate rules, we believe EPA should consider combining these into a single rulemaking for overall efficiency and because of the closely related nature of the issues that need to be addressed. At the very least, even if two rules are pursued, we urge EPA to expedite issuance of the rule establishing the CBI claim review plan so that reviews can begin as soon as possible after the list of active substances is compiled. This is important, given the long potential timeframe for EPA to complete its review of chemical identity claims for the "secret chemicals" on the TSCA Inventory, which could stretch out to 10 years post-enactment.[1] Much of the content of the second rule could be developed in advance of EPA compiling the final list of active substances.

If two rules are promulgated, section 8(b)(4) lays out a number of requirements that need to be incorporated into both rules, as well as aspects specific to one or the other:

- Inventory Reset rule
  - The requirements of sections 8(b)(4)(A) and (B) are expressly required to be included in this rule.
  - The requirements of sections 8(b)(5), (7), (8) and (9) should also be included in this rule.
- CBI Claim Review Plan rule
  - The requirements of sections 8(b)(4)(C), (D) and (E) are expressly required to be included in this rule.
  - The requirements of sections 8(b)(5), (7), (8) and (9) should also be included in this rule.

[1] 1 year to promulgate first rule + 6 months for companies to provide notices + 6 months [estimated] for EPA to compile active/inactive lists + 1 year to promulgate second rule + 5 years to execute review plan + 2-year extension = 10 years.

Specific comments

In developing the rule(s), EDF believes EPA need to do the following:

Make clear that no volume or other thresholds and no reporting exemptions apply to its Inventory reset.

The purpose of the requirement under section 8(b)(4)(A)(i) is to ensure EPA has a full and current list of all chemicals on the TSCA Inventory that are active in commerce. The currency and completeness of this list is paramount to many other aspects of the law, especially the prioritization and risk evaluation provisions of section 6 and, more generally, in providing an up-to-date understanding of the magnitude of chemical production and use within the scope of TSCA relevant to long-term planning and resource allocation.

While EPA has established various exemptions or volume or sales thresholds from reporting it has pursued under its section 8(a) authority, no such allowances are provided for under the section 8(b)(4)(A) amendments to TSCA. Rather, EPA is to:

- require manufacturers and allow processors to notify EPA of each chemical on the Inventory that they have manufactured or processed during the 10-year period preceding enactment; and
- require any manufacturer or processor of a chemical substance on the confidential portion of the Inventory that seeks to maintain an existing CBI claim for protection of the specific chemical identity of the chemical substance to notify EPA and include that request.

It should be noted that amendments to section 8(a) that added a new paragraph (5) specify several requirements EPA is to meet in carrying out all of section 8. Those requirements apply to the manner in which EPA is to require reporting (e.g., to avoid duplicative reporting and to minimize compliance costs for small manufacturers and processors) but do not pertain to or limit the scope of reporting, i.e., what entities are to be subject to such reporting, as long as such entities are "likely to have information relevant to the effective implementation of this title."

Make clear that processors who choose not to notify EPA of their recent processing of a chemical on the Inventory forgo their ability to request both that the chemical is designated active and that any existing CBI claim for protection of its identity is maintained.

While the notification called for under section 8(b)(4)(A)(i) is optional for processors, EPA's rule should make clear that any chemical a processor does not notice as being active will be designated as inactive if no other company designates it as active. The rule should also make clear that maintenance of any existing claim the company has made to protect the identity of a chemical will not be assured unless the company both files the notice required under section 8(b)(4)(A)(i) and includes a request that the claim be maintained, as required under section 8(b)(4)(B)(ii).

Make clear that only CBI claims for chemicals that are already confidential on the Inventory can be requested to be maintained.

Section 8(b)(8) states: "No person may assert a new claim under this subsection or section 14 for protection from disclosure of a specific chemical identity of any active or inactive substance ... that is not on the confidential portion of the list published under paragraph (1)."

EPA's rule or rules need to make clear that this limitation applies to claims under both sections 8 and 14.

Make clear that no *new* CBI claims can be asserted and requested to be maintained even for chemicals that are confidential on the Inventory.

With respect to CBI claims for the identity of chemicals companies have manufactured or processed that they seek to maintain, EPA's rule needs to specifically state that no company that had not previously asserted a CBI claim can assert one under the Inventory reset process, even for chemicals that are confidential on the Inventory. EPA also needs to require requesters to document ownership of their prior claims, and specify how that is to be done – *critical to ensure that new claims are not asserted through the Inventory reset process*. The law expressly provides only for requests to "maintain an existing claim," not to assert a new one; see section 8(b)(4)(B)(ii). EPA should make clear that any *new* claim to protect the identity of a chemical must be asserted and addressed through the procedures and requirements laid out in section 14; among other differences, the section 14 process would require EPA review of the claim within 90 days, and not the potentially much longer timeframe provided under this section.

EPA will also need to specify the nature and extent of substantiation that will be required to support the need to maintain such claims, which should be consistent with that required under section 14 for newly asserted CBI claims.

Specify the substantiation and record-keeping requirements applicable to companies' identification of active chemicals.

EPA's rule needs to delineate the documentation companies need to have to support their identification of chemicals they have manufactured or processed during the past 10 years. It should also clarify whether that information needs to be submitted to EPA or be available upon request, and for how long such records need to be kept.

Specify a deadline by which it will identify all active and inactive chemicals on the Inventory.

Section 8(b)(4)(A)(ii) and (iii) require EPA to identify active and inactive chemicals on the Inventory based on the notices received in response to its rule. That rule needs to specify a maximum timeframe

for carrying out this action, which EDF believes should be as soon as practicable and not exceed 1 year after promulgation of the rule, providing EPA 6 months to compile the lists of active and inactive chemicals.

Specify a deadline by which it will disclose the identities of active chemicals for which it does not receive any requests to maintain confidentiality.

Section 8(b)(4)(B)(iv) requires EPA to "move any active chemical substance for which no request was received to maintain an existing claim for protection against disclosure of the specific chemical identity of the chemical substance as confidential from the confidential portion of the list published under paragraph (1) to the nonconfidential portion of that list."

EPA's rule should specify a maximum timeframe for carrying out this action, which we believe can and should be done at the same time as EPA identifies active and inactive chemicals on the Inventory (i.e., within 6 months of receiving all notifications and claims).

Specify the timing and content of companies' substantiation of CBI claims they seek to maintain.

Section 8(b)(4)(D)(i) mandates EPA to require all manufacturers and processors that seek to maintain existing CBI claims for the specific chemical identities of active chemicals on the confidential portion of the Inventory to substantiate those claims, "at a time requested by the Administrator" – unless that person has substantiated that claim in another submission during the 5 years preceding EPA's request for substantiation.

EPA's rule needs to address two issues in this regard. First, EPA needs to lay out how it will stage each request for substantiation and its associated deadlines, which need to come sufficiently in advance of EPA's review of a given CBI claim so as not to delay the process.[2] EPA could usefully tie the timing of these steps to the annual goals it sets for claim reviews pursuant to section 8(b)(4)(E)(ii)(II).

Second, with respect to any alternative prior substantiation on which a claimant seeks to rely, EPA needs to specify the types of chemical identity claims in other submissions for which it expects such prior substantiations will qualify as sufficient, i.e., where the substantiations adequately represent the current situations and where the context for those claims and substantiations are similar enough to this context as to be "transferable." EPA's rule also needs to require that those other substantiations fully meet the requirements for substantiation specified in sections 8 and 14 of the new law.

[2] Our understanding of the reason the law does not require substantiation at the time of assertion of such claims is to ensure the substantiations are current, which might not be the case had the substantiations been submitted years before EPA's reviews of the claims.

Indicate how it will pace its reviews under the review plan so as to meet the 5-year deadline and minimize the likelihood of needing an extension.

Section 8(b)(4)(E) requires EPA is to pace its reviews so as to complete all required reviews within 5 years , unless it publicly justifies why it needs up to a 2-year extension due to a large number of such claims. EPA is also to publish annual goals for and report its progress in reviewing the claims.

EPA's rule should establish the process EPA will use to pace the reviews to ensure all applicable CBI claims are reviewed within 5 years of EPA's publication of the list of active substances. The annual goals should reflect a pace that is sufficient and transparent in its intent to meet the 5-year deadline. EPA should also explicitly describe under what circumstances (hopefully unlikely) it would need to extend the review period.

EPA's rule should also specify a deadline by which it will review any chemical identity CBI claims asserted by companies when they notify EPA of their intent to commence manufacture or processing of an inactive chemical, pursuant to section 8(b)(5). The law requires that EPA "promptly" review and make a decision on any such claim, based on substantiation of the claim required to be submitted by the claimant no later than 30 days after asserting the claim. EDF believes that such deadline should be no more than 30 days, consistent with the 30-day deadline for EPA reviews of renewal requests for CBI claims under section 14(e)(2).

Integrate claims asserted and reviewed under section 8 into the procedures and systems it develops for chemical identity claims asserted and reviewed pursuant to section 14.

A number of provisions under section 14 apply to the assertion, substantiation, review, assignment of unique identifiers and tracking of CBI claims for chemical identity, including those under section 8. EPA's rule or rules need to make clear that those requirements apply, and how they will be applied. EPA should fully integrate claims reviewed under section 8 into the systems it develops pursuant to section 14. This should extend both to claims reviewed under the 5-year review plan and claims reviewed in association with the shift of a chemical from inactive to active status.

Specify how it will decide whether or not it is necessary to determine the priority of a newly activated chemical.

Section 8(b)(5)(B)(iii)(IV) requires EPA to determine the priority (high or low) of a newly activated chemical "as the Administrator determines to be necessary."

EPA's rule needs to specify how it will make this determination, including the process and timeframe under which it will do so. EDF believes the same criteria should apply as EPA will use for prioritization decisions for already active chemicals, in order to ensure a level playing field.

Make clear that the public information requirements of section 8(b)(7) apply to chemical identity claims under both sections 8 and 14.

Section 8(b)(7) delineates a number of requirements, including some that are applicable to Inventory listings made pursuant to that subsection, under which authority the Inventory is established and required to be maintained. While the placement of these requirements under section 8(b) is logical given its applicability to Inventory listings, some of the requirements are broader than just Inventory listings. For example, EPA is required to make public unique identifiers and other identifying information on chemicals that have not traditionally been included on the Inventory.

EPA's rule should specify how such information will be made available, and the timeframes and deadlines that will apply to EPA's updates of both the Inventory and other required public listings. It should also make clear that these listing requirements extend to chemical identities associated with CBI claims asserted and reviewed under section 14 as well as section 8.

[end]