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Resetting the TSCA Inventory: Why This Is Important

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On August 11, 2017, the US Environmental Protection Agency (EPA) published the third Toxic Substances Control Act (TSCA) framework final rule in the *Federal Register*, the TSCA Inventory Notification (Active-Inactive) Requirements (EPA, 2017). This final rule is now in effect. This *Washington Watch* column explains why the rule is important, and what stakeholders should be doing to protect their interests.

Background

Under old TSCA, the list of chemicals believed to be in commerce and listed on the TSCA Chemical Inventory was widely viewed as outdated and greatly overstated the chemicals in active commerce. While the chemicals listed on the Inventory may at one point have been commercially active, it had long been thought that many, even most, of the 85,000 or so listed chemical substances were no longer in use. Under new TSCA, Congress authorized EPA to "reset" the Inventory by distinguishing between active and inactive substances. By so doing, EPA and the public would obtain a clear subset of chemicals in active use in the United States and on which EPA could better focus its efforts to prioritize chemical substances for risk evaluation and risk mitigation purposes.

As explained below, the final TSCA Inventory notification rule establishes a retrospective electronic notification of chemical substances listed on the TSCA Inventory that were manufactured (including imported) for nonexempt commercial purposes during the 10-year time period ending on June 21, 2016, with provisions also to allow notification voluntarily by processors. EPA will use these notifications to distinguish active substances from inactive substances.

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Reportable Chemical Substances and Activities

The retrospective reporting requirements apply to chemical substances listed on the TSCA Inventory that were manufactured for nonexempt commercial purposes during the 10-year period ending on June 21, 2016. EPA notes that this "lookback period" is set by new TSCA (EPA, 2017, page 37523). The forward-looking reporting requirements apply to substances listed as inactive on the Inventory that are to be reintroduced into United States commerce for nonexempt purposes.

The scope of chemical substances covered under the final rule is reflected in the definitions of "chemical substance subject to commercial activity designation" and "reportable chemical substance" that exclude substances that are not chemical substances and substances that are not listed on the Inventory (EPA, 2017, page 37523). For example, according to EPA, a substance that is not considered a "chemical substance" is not a "chemical substance subject to commercial activity designation" or a "reportable chemical substance," and it thus cannot become an "active substance" or an "inactive substance" (EPA, 2017, page 37523). A similar analysis applies with respect to a mixture, although EPA notes that individual Inventory-listed substances present in the mixture may be subject to reporting. Additionally, a substance that has not been added to the Inventory because it is manufactured solely under a TSCA Section 5(h) exemption (*e.g.*, low release and low exposure exemption, low volume exemption (LVE), polymer exemption, research and development exemption, test marketing exemption) is not a "chemical substance subject to commercial activity designation" or a "reportable chemical substance" and it cannot become an "active substance" or an "inactive substance" (EPA, 2017, page 37523). Naturally occurring chemical substances also are excluded from reporting provided the manufacturing and processing of such substances meet certain criteria. EPA states that it is designating the category of "Naturally Occurring Chemical Substances" as active substances, thereby excluding them from reporting (EPA, 2017, page 37523). .

Manufacturing or processing a chemical substance listed on the Inventory solely for an exempt commercial purpose is not subject to reporting requirements. EPA states that while it expects that many chemical

substances manufactured or processed for exempt commercial purposes will not be listed on the Inventory (due to similar exemptions under premanufacture notification (PMN) regulations), and therefore are already excluded from reporting, the activity exemptions listed at 40 Code of Federal Regulations (CFR) Section 710.27(a) clarify circumstances under which a person is exempt from reporting requirements for the manufacturing or processing of a chemical substance that has been listed on the Inventory (*e.g.*, due to another manufacturer's actions).

The final rule establishes an exemption from the retrospective reporting requirement for three different circumstances in which EPA has already received equivalent notice that a chemical substance was manufactured during the lookback period, and further requirement to submit a notice would therefore be inconsistent with new TSCA Section 8(a)(5)(B):

(1) Chemical substances that are on the interim list of active substances described in new TSCA Section 8(b)(6) will be designated as active substances, by operation of the final rule, and they are exempted from retrospective notification requirements. The interim list will be available on the TSCA Inventory web page (*see* https://www.epa.gov/tsca-inventory), and is comprised of all chemical substances reported in 2012 or 2016 under the Chemical Data Reporting (CDR) rule (EPA, 2017, page 37523) ;

(2) Chemical substances added to the Inventory during the ten-year time period ending on June 21, 2016, pursuant to a Notice of Commencement (NOC) under 40 C.F.R. Section 720.102 received by EPA between June 21, 2006, and June 21, 2016, will be designated as active substances, by operation of the final rule, and they are exempted from retrospective notification requirements under the rule. An NOC is required to be submitted on or no later than 30 calendar days after the first day of manufacture for commercial purpose. Additionally, an NOC substance is considered to be added to the Inventory on the date the NOC is received by EPA, provided that EPA determines the NOC to be valid during its review (EPA, 2017, page 37523); and

(3) A manufacturer is exempt from the retrospective notification requirements under the rule, for a particular chemical substance, if the manufacturer has evidence in the form of a Central Data Exchange (CDX)

receipt, documenting EPA's receipt of a [Notice of Activity (NOA)] Form A from another manufacturer. *See* 40 C.F.R. Section 710.25(a). EPA notes that manufacturers "bear the risk of failing to submit a required forward-looking notification (NOA Form B) notice if they rely on this Form A exemption, and the Form A notice (for which they have a CDX receipt) is later withdrawn, leading to the substance being designated as inactive" (EPA, 2017, page 37524).

EPA states that persons who manufactured or processed a chemical substance listed on the confidential portion of the Inventory, which was added to the Inventory prior to June 22, 2016, should recognize that they must submit an NOA Form A if they wish to indicate that they "seek to maintain an existing claim for protection against disclosure of the specific chemical identity of the substance as confidential" (EPA, 2017, page 37524). This includes persons that, during the lookback period, manufactured or processed a confidential substance on the Inventory for which EPA already has an equivalent notice. It may also potentially include persons that, during the lookback period, manufactured or processed a confidential substance on the Inventory for an exempt commercial purpose, if such substance is designated active due, for instance, to EPA's receipt of an equivalent notice (such as an NOC or CDR report). In connection with extending manufacturers' reporting exemptions to cover substances on the confidential portion of the Inventory, EPA states that it revised 40 CFR Section 710.25(b) to clarify manufacturers' and processors' discretion to report. If manufacturers elect not to submit a notice because they are availing themselves of one of the exemptions described above, "then they are foregoing their opportunity to maintain an existing claim for protection against disclosure of the specific chemical identity of the substance as confidential" (EPA, 2017, page 37524). EPA notes that it is required, by statute, to move from the confidential to the public portion of the Inventory any active chemical substance for which no request is received to maintain an existing confidential business information (CBI) claim for chemical identity.

Chemical substances added to the Inventory on or after June 22, 2016, will be designated as active, and such substances are not subject to reporting under the rule. Furthermore, according to EPA, such substances are beyond the scope of the CBI claim maintenance provision under new TSCA Section

8(b)(4)(B)(ii). This CBI maintenance provision is intended to address "existing claim[s] for protection against disclosure of the specific chemical identity." EPA states that it interprets this "to be a reference to CBI claims asserted prior to June 22, 2016" (EPA, 2017, page 37523).

Timing of Reporting

Pursuant to the rulemaking, the retrospective reporting period for manufacturers begins on August 11, 2017, and ends on February 7, 2018. The submission period for processors also begins on August 11, 2017, but processors have until October 5, 2018, to submit retrospective activity notifications. According to EPA, the 180-day time period for this retrospective reporting for manufacturers is the maximum time allowed under new TSCA Section 8(b)(4)(A). Following this retrospective reporting for manufacturers, EPA will include the active designations, determined by the notices received, on a draft of the Inventory. EPA will publish the draft Inventory with the active designations "as soon as is practicable" following the close of the 180-day submission period. The draft Inventory will not have the legal effect of actually designating any chemical substance as inactive, however, and EPA does not construe it as the list with "designations of active substances and inactive substances" (EPA, 2017, page 37524) from which forward-looking reporting commences. EPA states that it concludes that new TSCA is referring to the completed product of the initial cycle of sorting between active and inactive substances, not the preliminary product of the initial cycle of such sorting.

Processors may report to EPA not later than 420 days after the final rule is published in the *Federal Register,* or by October 5, 2018. Processors have the option "to simply not report under TSCA section 8(b)(4) and continue processing until the effective date of EPA's designation of a chemical substance as inactive on the Inventory" (EPA, 2017, page 37524). At such time, any further processing of the substance for a nonexempt commercial purpose, without prior notification to EPA, will be prohibited by new TSCA Section 8(b)(5). EPA notes that earlier notification under new TSCA Section 8(b)(4) will allow EPA to add the substance to the Inventory as an active substance, so that processing can continue without the need for a later notification.

The forward-looking reporting period begins on the effective date of EPA's final active/inactive substance designations. Manufacturers and processors intending to reintroduce into US commerce for a nonexempt commercial purpose a chemical substance designated as inactive on the Inventory must report to EPA not more than 90 days before the anticipated date of manufacturing or processing.

EPA states that the structure of the reporting requirements under new TSCA Sections 8(b)(4)(A) and 8(b)(5)(B) results in a transitional period beginning on June 22, 2016, (the day after the lookback period for retrospective reporting ends), and ending on the date that EPA designates chemical substances on the Inventory as active or inactive (the day that forward-looking reporting begins). It is possible that substances that were not manufactured or processed during the lookback period -- and therefore cannot be designated as active through retrospective reporting -- may be reintroduced into US commerce during this transitional period. In response to comments, EPA is establishing an effective date provision for the designation of a chemical substance as an inactive substance. As "inactive substance" is now defined, a substance is not considered to be "inactive" until 90 days after EPA has designated the substance as inactive. EPA states that it will identify chemical substances for inactive designation in a signed action accompanying the first version of the Inventory with all final active-inactive listings.

Accordingly, the final rule clarifies that the obligation to submit an NOA Form B does not arise until 90 days after EPA has identified chemical substances for the inactive designation. The rule also clarifies that manufacturers and processors will be permitted to submit an NOA Form B for a substance that EPA has identified for inactive designation, before the effective date of such designation, and thus before the substance has the legal status of being inactive.

Information to Be Reported

Manufacturers reporting for the retrospective reporting period must provide chemical identity information and indicate whether they seek to maintain an existing claim for protection against disclosure of a CBI chemical identity, if applicable. EPA did not issue in final the proposed requirements to report

commercial activity type and date range. The final rule clarifies that persons required to report will provide information to the extent it is known to or reasonably ascertainable by them. EPA states that it is not establishing a formal corrections provision in the regulation, but will allow a manufacturer or processor to withdraw an NOA Form A, provided that the withdrawn notice is submitted prior to the end of the submission period for processors (*i.e*., not later than 420 days after the final rule is published in the *Federal Register)*. The manufacturer may effect a correction by filing a new NOA Form A following withdrawal, so long as the new Form A is filed within the time provided in the rule for the initial filing (*i.e*., no later than 180 days after the final rule is published in the *Federal Register*).

EPA states that processors that choose to report for the retrospective reporting period will be required to provide chemical identity information and whether they seek to maintain an existing claim for protection against disclosure of a CBI chemical identity, if applicable. EPA removed the proposed requirements to report commercial activity type and date range as these requirements were deemed unnecessary to achieve the objective of designating substances as active or inactive on the Inventory. EPA states that it is not establishing a formal corrections provision in the regulation for an NOA Form A, but will allow a processer to withdraw an NOA Form A, provided that the withdrawn notice is submitted not later than 420 days after the final rule is published in the *Federal Register*. As with manufacturers, EPA notes that processors can effectuate a correction by filing a new Form A within the time provided in the rule for the initial filing (*i.e*., no later than 420 days after the final rule is published in the *Federal Register*).

The final rule requires that persons that intend to manufacture or process an inactive substance for nonexempt commercial purpose provide chemical identity information, the anticipated date of manufacturing or processing for nonexempt commercial purpose, and whether they seek to maintain an existing claim for protection against disclosure of a CBI chemical identity, if applicable.

EPA received requests that submitters be able to withdraw an NOA Form B if their intent to re-commence manufacture or process of a chemical substance later changes. In response, EPA will allow a submitter to request to withdraw

its NOA Form B, and EPA may do so, if EPA has not yet altered the Inventory status of the substance in response to the original submission (*i.e.*, EPA has neither re-designated the substance from inactive to active nor moved the substance from the confidential portion of the Inventory to the public portion of the Inventory as a result of a request in the original submission for a CBI claim to be withdrawn). EPA notes that because another person may have commenced manufacturing or processing for nonexempt commercial purpose in reliance on a substance being re-designated as active, the rule does not allow for EPA to revert a substance re-designated as active back to inactive status based on a request to withdraw an NOA Form B, or for EPA to revert a non-CBI substance back to a CBI substance based on a request to withdraw a Form B.

The NOA Form A will be used by manufacturers for the retrospective reporting period. It will also be used by processors who choose to report for the retrospective reporting period. The NOA Form B will be used by manufacturers and processors for forward-looking reporting, which includes reporting chemical substances reintroduced into US commerce during the transitional period.

Submission of Information to EPA

The final rule requires electronic reporting similar to the requirements established in 2013 for submitting other information under TSCA. Submitters will use EPA's CDX and EPA's Chemical Information Submission System (CISS), a web-based reporting tool, for all reporting under the rule. EPA states that it expects that electronic reporting will minimize time requirements, support improved data quality, and provide efficiencies for both submitters and EPA.

CBI Claims and Requests

Notices pursuant to the rule may contain two different types of CBI assertions: claims for protection of information other than specific chemical identity, and requests to maintain existing claims for protection of specific chemical identity. EPA states that it extensively re-wrote the substantiation questions from the proposed rule in a manner intended to secure more

succinctly responses for CBI assertions of discrete data elements, as well as CBI concerns on the linkage of data elements.

For all new claims for protection (*i.e.*, for all CBI assertions other than requests to maintain existing claims for protection of specific chemical identity), new TSCA Section 14(c)(1)(B) and 14(c)(5) require that persons claiming CBI must provide a specific certification statement regarding the basis for the CBI claims. In addition, new TSCA Section 14(c)(3) and this rule require that all such claims be substantiated at the time of submission. EPA will review a representative subset of these claims as specified by new TSCA Section 14(g)(1).

Any manufacturer or processor submitting an NOA under new TSCA Section 8(b)(4)(A) may seek to maintain an existing CBI claim for specific chemical identity, regardless of whether that person asserted the original claim that caused the specific chemical identity to be listed on the confidential portion of the Inventory. EPA states that it believes this is the correct interpretation of "a manufacturer or processor . . . that seeks to maintain an existing claim for protection against disclosure" of specific chemical identity in new TSCA Section 8(b)(4)(B)(ii). According to EPA, "[a] number of manufacturers and processors may legitimately benefit from the confidential status of a specific chemical identity, even when such persons did not originally report that chemical identity to EPA and therefore were not in a position to assert a CBI claim for that chemical identity" (EPA, 2017, page 37527). EPA does not believe that Congress intended for specific confidential chemical identities to be disclosed without providing the opportunity for manufacturers and processors to make a request that the identities should remain confidential simply because the original claimants did not file under new TSCA Section 8(b)(4)(B)(ii).

Pursuant to new TSCA Section 8(b)(4)(B)(iv), EPA will move an active substance from the confidential portion of the Inventory to the non-confidential portion if no manufacturer or processor submitting an NOA under new TSCA Section 8(b)(4)(A) requests to maintain the existing CBI claim for the specific chemical identity of that chemical substance. EPA states that, as a courtesy, its practice is to notify original claimants and/or the public when it has moved substances from the confidential portion of the Inventory to the public portion of the Inventory, (*e.g.*, through direct contact

with the original claimant or publication of a *Federal Register* notice). A chemical substance for which EPA has received a request to maintain an existing CBI claim for specific chemical identity will remain on the confidential portion of the Inventory pending EPA's review of the claim pursuant to a review plan to be promulgated at a later date.

While the final rule requires submitters to indicate whether they seek to maintain an existing CBI claim for specific chemical identity, the rule does not include mandatory substantiation requirements for CBI requests for specific chemical identity on an NOA Form A. New TSCA Section 8(b)(4)(B)(iii) stipulates that EPA shall "require the substantiation of those claims pursuant to section 14 and in accordance with the review plan described in subparagraph C" (EPA, 2017, page 37527). EPA states that it will conduct a separate rulemaking to establish this review plan. The review plan will include mandatory requirements for substantiating a CBI request for specific chemical identity reported in an NOA Form A and specify when such substantiation is to be provided. If EPA receives an NOA Form A in which the submitter requests to maintain an existing CBI claim for specific chemical identity but chooses not to substantiate such at the time of filing, EPA will continue to list the chemical substance on the confidential portion of the Inventory pending the submission of any substantiation required under the review plan and EPA's review of the claim pursuant to the review plan.

EPA notes that under the rule, it is allowing companies to submit substantiation for the CBI claims for specific chemical identity at the same time that the NOA Form A is filed, however, if they so choose. Provided the period between the date these earlier substantiations are received and the due date to be established in the review plan (yet to be proposed) is not more than five years, these substantiations will exempt the company from the requirement to submit additional substantiation under the terms of the review plan.

With respect to requests to maintain existing CBI claims that are submitted on an NOA Form B, new TSCA Section 8(b)(5)(B) stipulates that such requests must be substantiated not later than 30 days after submitting Form B. Substantiation requirements for NOA Form B CBI claims for specific chemical identity are found in 40 CFR Section 710.37(a)(2). EPA states that

it will allow companies to submit substantiation at the same time that their NOA Form B is filed, if they so choose.

Discussion

The final rule is thoughtful and well crafted. EPA's decision to withdraw its proposal to include the activity type and dates of activity was the right one recognizing that the required recordkeeping provides EPA the necessary documentation of the reported commercial activity. The proposal to require dates of activity was especially problematic because records older than five years may not be routinely available and the nature of some manufacturing, processing, and importing practices are highly variable making it difficult for reporters to specify a date range.

Importantly, EPA clarified which substances must be reported. EPA recognized that any substance for which an NOC was filed in the lookback period satisfies the requirement to demonstrate commercial activity and EPA will add such substances to the list of interim active substances that already included substances reported under the 2012 or 2016 CDR cycles. EPA disagreed with commenters who argued that polymers listed on the Inventory should be designated as active substances. EPA stated that new TSCA required reporting on all substances manufactured during the lookback period; there is no exemption for low hazard substances or substances that might be eligible for an exemption.

EPA further clarified that substances that are not listed on the Inventory but are manufactured under an exemption are exempt from NOA reporting. In the case that a company currently manufactures a substance under an exemption (*e.g.*, an LVE), if the substance is listed on the public portion of the Inventory, the company is required to submit an NOA. On the other hand, if a company manufactures a substance under an LVE that may be listed on the confidential portion of the Inventory, the company need not determine the Inventory status through a *bona fide* intent notice and the company is exempt from NOA reporting. In summary, if a substance is manufactured under an exemption (*e.g.*, LVE or polymer exemption) and the substance is not known to the manufacturer to be listed on the Inventory, an NOA is not required.

A critical problem that EPA addresses in the final rule relates to the transition period between June 22, 2016, and when the list of active substances is published. The proposed rule required an NOA for activity in the lookback period (prior to June 22, 2016) and NOA submission for inactive substances after the publication of the list of active substances. There was no provision for an NOA for commercial activity that occurred between June 22, 2016, and the publication of the list of active substances. That is, a manufacturer that commenced importing an existing chemical substance in January 2017 had no mechanism to report such activity to EPA and, if no other company reported the substance as active, could find itself importing an inactive substance when the final list is published. To prevent this situation, EPA has implemented a 90-day period after the final list is published in which manufacturers can submit a prospective (Form B) NOA for a substance that appears as inactive on that list.

EPA responded to concerns about the meaning of "known or reasonably ascertainable," especially as the term relates to company mergers, acquisitions, and divestitures. EPA provided additional guidance and refers to the guidance published to support the 2016 CDR reporting cycle. In particular, EPA rejected the argument that information that is not "readily obtainable" meets the definition of not known or reasonably ascertainable.

Publication of the rule is just the first step in resetting the Inventory. Now the hard work begins, and submitters need to prepare their submission, and EPA will need to prepare to process these submissions. Although it will take a lot of effort, a reset Inventory is an important product of the new TSCA, and well worth the effort. For the first time in a long time, we will have a chemical Inventory that more accurately reflects chemicals in commerce.

References

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