Questions and Answers

We hope that you found Bergeson & Campbell, P.C.'s (B&C®) recent Bloomberg BNA™ -- hosted webinar on the Toxic Substances Control Act (TSCA) Inventory notification rule valuable. We received many questions during the webinar and we provide answers below to the extent we are able to do so based on the rule itself and applicable regulations. A number of the questions can be answered only by the U.S. Environmental Protection Agency (EPA) and, while the questions are included below, we have provided them to EPA as follow-up to give EPA source material for developing guidance to clarify issues and inform regulated entities of the requirements under the reporting rule.

B&C was pleased to sponsor the two recent BNA webinars at no charge to participants. We see this as a logical outgrowth of our considerable efforts over the past year in analyzing the law and EPA's interpretation and application of it, and in working to assist EPA and other stakeholders during this critical early period in the new law's implementation. The fact that over 500 participants signed up for the most recent webinar demonstrates that there is a need for and an interest in obtaining quality information and understanding on the new law.

While good advice can be obtained from numerous sources, we believe that B&C is uniquely equipped to provide thoughtful and informed advice and recommendations to its clients. Our staff is unique in the depth and breadth of its TSCA experience, including highly experienced experts, both former EPA officials and outside experts, who have made a career in TSCA implementation in areas including the Inventory, risk assessment, risk management, and legal and policy approaches. If you can use help in meeting the requirements under the Inventory notification rule, or in any other areas under new TSCA, please contact us.

Questions

Can TSCA reset reports be submitted by CDX or paper?

Form A and Form B notices must be submitted via the Central Data Exchange (CDX).

If a company was previously active early in the covered period, but no longer considers a substance as commercially active (*e.g.*, sold the business or "killed" the substance), do they report as "active," "inactive," or not at all?

If the company divested from the business, the success-in-interest is responsible for active notice reporting. If, on the other hand, the company simply ceased manufacturing or importing, the company must submit a Form A.

For example: Company X manufactured a substance from 1985 to 2007 but, because of low demand, stopped manufacturing the substance. Because commercial activity (manufacturing) occurred during the lookback period, Company X is required to submit a Form A.

Company Y manufactured a substance from 1990-2010 when Company Y divested from that business line. The business line was sold to Company Z. In this case, Company Z is required to submit a Form A for the substance.

If a substance qualifies for an exemption (Ex. polymer), is there an issue to notify it as ACTIVE anyway?

Yes. Polymers that are listed on the Inventory must be reported, regardless of the polymer's eligibility for an exemption. If a polymer is manufactured under a polymer exemption (40 C.F.R. § 723.250) and the polymer is not listed on the Inventory, the polymer is exempt from reporting.

For polymers exempt from CDR reporting, are these same substances exempt from the TSCA Active-Inactive Rule?

Polymers that are listed on the Inventory must be reported if active. Polymers manufactured under the polymer exemption criteria (40 C.F.R. § 723.250) that are not listed on the TSCA Inventory are exempt from reporting.

If a company decided in the past not to obtain a CAS Number for a polymer meeting the polymer exemption, are we now required to get one to check if it has been placed on the TSCA Inventory?

As noted above, polymers that are listed on the Inventory must be reported if active. Polymers manufactured under the polymer exemption criteria (40 C.F.R. § 723.250) that are not listed on the TSCA Inventory are exempt from reporting.

If a company relied on the polymer exemption in the past, and is unsure if the polymer has subsequently been added to the Inventory by another company, it would need to rely on "known or reasonably ascertainable" information to determine if an active notification is required. EPA is likely of the view that the Chemical Abstracts Service (CAS) Number of a polymer manufactured under the polymer exemption is "reasonably ascertainable." The company could conduct a search of the Inventory for the polymer or confer with CAS' Inventory Expert Service (IES) on whether a CAS Number already exists for the polymer. The company is not required to obtain a new CAS Number if one does not already exist.

Is there a *de minimis* volume for reporting?

No. Any amount manufactured or imported for a non-exempt purpose is reportable.

What volume triggers the inventory notifications for active chemicals?

There is no volume trigger. Any amount manufactured or imported for a non-exempt purpose is reportable.

Do you know if CDX is up and running for notifications to begin?

The active notice data flow is not yet available in CDX. It is scheduled to go live the day the final rule is published in the *Federal Register*.

Is Form A currently available to view in CDX?

There is a draft Form A in the rule docket, but the form has been changed in the final rule to reflect the more limited set of information that will be required. The final form will be available when the rule is published.

Does only the original submitter (or successor) of a substance to the confidential Inventory have standing to assert CBI as part of Inventory reset?

Any manufacturer or importer reporting a Form A may request to maintain a confidential business information (CBI) identity, but must substantiate the CBI claim. Each company that can substantiate a need to protect a CBI identity should file their own Form A to ensure that the company's interest is protected. A company that relies on another's CBI claim may lose the protection if the claimant withdraws the claim or allows the claim to lapse.

Do you expect that substantiation for CBI as a submitter and technical contact only to be less burdensome than CBI substantiation for a substance identity?

The substantiation questions are the same for the "submitter" and "technical contact" information elements. The substantiation questions for "chemical identity" are not exactly the same, but are generally similar, so there should not be a significant difference in the effort. The level of difficulty in responding to any of the required substantiation questions will be based on the availability of facts and context to support the CBI claim(s).

Can a foreign entity co-submit to CDX with the U.S. supplier directly, or does the foreign entity need to use a U.S. entity?

A U.S. entity (presumably the importer of record) must submit the Form A. The importer may submit a joint Form A if the importer does not know the identity of the substance. In that case, a foreign supplier may submit the identity directly to EPA.

For example: U.S.-based Company X purchases a monomer from a foreign supplier, Company Y, who imported the monomer to the U.S. during the look-back period. Company X does not know the identity of the monomer. Company X initiates a joint Form A as a Primary Authorized Official (AO) and fills out the information in Company X's possession (the identity of all monomers except the monomer that is CBI); Company X then sends the joint submission identifier to Company Y. A Secondary AO at Company Y submits the monomer identity directly to EPA. EPA processes both the primary and secondary submissions to determine the identity of the polymer and indicate that polymer identity as active. Each company must substantiate any CBI claims made in their own Form A submissions.

For companies with multiple locations, should the retrospective reporting be completed as one entity (or by each location)?

Only one Form A is required from a company regardless of the number of sites that manufacture or import a substance.

Must reporting be done by company or by site?

A company must report whether a substance was manufactured or imported. A company is only required to submit one Form A per substance regardless of the number of sites.

If a PMN was submitted on a new substance and there was no CAS Number requested at the time of submission, but a CAS Number is now available for the substance, is there a way we can report that CAS Number to EPA if we are no longer maintaining a CBI claim?

In this instance, the entity would report the substance using the accession number, but would not claim the identity as confidential.

Although not required, is it ok to report an ID for chemicals which were reported in the 2012 and 2016 CDR?

Yes. Such substances are exempt from reporting, but not prohibited.

If you are importing a substance for R&D purposes that is currently listed on the TSCA Inventory (so no non-TSCA recordkeeping is required), but the company does not notify the substance as active, will there be any recordkeeping requirements for that R&D material that will now be on the inactive inventory?

Importing under the research and development (R&D) exemption is not affected by active/inactive status. Active notices (Form A or B) are only required for nonexempt commercial purposes. Recordkeeping related to the R&D exemption should be maintained.

An equipment manufacturer is likely to be both a processor and a user, not just a processor. For example, a "use" would be using a solvent to clean equipment, but the solvent is not incorporated into the equipment or sold to a customer.

Yes. The equipment manufacturer in this scenario is not obligated to submit a Notice of Activity (NOA), but should ensure that the substance is listed as active.

For the look back period, is the test on a legal entity basis? What if a new company purchased the operating assets of a prior liquidated entity?

The successor-in-interest acquires the obligation.

EPA has been reiterating its 2016 Chemical Data Reporting (CDR) guidance for complex reporting scenarios. EPA published guidance on "Reporting After Changes to Company Ownership or Legal Identity"[1] as guidance for the 2016 CDR reporting cycle. This scenario and a number of others are discussed in that guidance document.

Is EPA CDX currently set up to start Form A reporting?

The active notice system and XML schema are scheduled to be released the day the final rule is published in the *Federal Register*.

Do we have to submit a Form A or B if we submitted the information via CDR 2016?

Presumably the substance is listed as interim active. If that status is confirmed, an active notice is not required. If the substance identity is confidential, the entity must submit a Form A to maintain the CBI claim.

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[1] Available at https://www.epa.gov/chemical-data-reporting/fact-sheet-reporting-after-changes-company-ownership-or-legal-identity.

What type of documentation is recommended if information is not available for all of the look back period?

TSCA regulations require that records of manufacturing or importing must be maintained for five years; presumably each manufacturer/importer can document activity over the past five years and perhaps longer. If an entity has records of activity (including sales and marketing information) in the first five years of the look-back period, or employees have "reasonably ascertainable" knowledge of manufacturing or importing in that timeframe, a Form A is required.

In any case, reporters must maintain records of activity, including records documenting reporting exemptions, for five years from the end of the active notice reporting period.

Wasn't the interim inventory active substances published already?

Yes; it was published a couple of weeks ago and is available at https://www.epa.gov/tsca-inventory/interim-list-active-substances.

How can a processor confirm that an importer has filed an NOA?

If the manufacturer or importer provides a CAS Number or accession number, the processor can search the active list that will be published after the manufacturer's reporting period.

Since a processor is not REQUIRED to report, and will be able to review the interim active list before deciding if the processor wants to report, isn't the CDX receipt irrelevant?

Yes. For processors, what matters is whether a substance is or is not on the interim active list. A copy of a CDX receipt provides an exemption from reporting by a manufacturer or importer.

Any indication of when the IT tools will be available to submit Form A? Same question for the XML upload tool for multiple substances?

EPA to answer.

Is there any indication when the reporting module will be available on CDX?

EPA to answer.

Any idea why the final inventory rule has not been published in *Federal Register* yet? Any inkling as to when the final inventory rule is likely to be published?

EPA to answer.

How much checking are we required to do for polymers with multiple monomers under the 2% rule?

EPA to answer.

Does EPA intend to beta test the CDX reporting module and XML template with industry?

EPA to answer.

Can Form A CBI be submitted on CDX?

EPA to answer.

Will the name of the substance be on the CDX receipt from EPA?

EPA to answer.

Once a Form B is submitted, can you commence activity sooner than the intended date?

EPA to answer.

Can a CBI substantiation be applied to several chemicals during CDX input?

EPA to answer.

How many staff members does EPA have to review CBI claims?

EPA to answer.

Earlier this week, EPA published a list of "no unreasonable risk findings." Most of the listings of chemicals included in that notice include the notation "polymer exemption flag." What does that mean/signify?

EPA to answer.

Is Jeff going to become Acting AA upon Wendy's departure?

EPA to answer.

What submissions have been found to not support CBI claims?

EPA to answer.

For PMN consultations, would a face-to-face or a web-based meeting be preferred?

EPA to answer.