

BNA Insights

CHEMICALS

President Barack Obama signed into law amendments to the Toxic Substances Control Act on June 22, 2016. The amendments bring sweeping changes to the nation's primary chemicals law. In this Bloomberg BNA Insights, Kathleen M. Roberts, Richard E. Engler, Charles M. Auer, and Lynn L. Bergeson look specifically at the changes to Section 8, which regulates record keeping and reporting obligations.

An Analysis of Section 8 of the New Toxic Substances Control Act

BY KATHLEEN M. ROBERTS, RICHARD E. ENGLER,
PH.D., CHARLES M. AUER, AND LYNN L. BERGESON

The Frank R. Lautenberg Chemical Safety for the 21st Century Act significantly amends the Toxic Substances Control Act (TSCA), particularly with regard to Section 8 record keeping and reporting obligations. The act, identified as Pub. L. No. 114-182, was signed into law by President Obama on June 22, 2016.

Kathleen M. Roberts is vice president of Bergeson & Campbell PC's (B&C[®]) Consortia Management LLC (BCCM). Ms. Roberts provides cost-effective administrative and management services to industry groups engaged in regulatory advocacy, ensuring that their interests are protected and their voices are heard.

Richard E. Engler, Ph.D. is a senior chemist with B&C. Dr. Engler is a 17-year veteran of the Environmental Protection Agency and is one of the most widely recognized experts in the field of green chemistry, having served as senior staff scientist in the EPA's Office of Pollution Prevention and Toxics (OPPT) and leader of the EPA's Green Chemistry Program.

Charles M. Auer is president of Charles Auer & Associates LLC. Mr. Auer was formerly the director of the EPA's OPPT from September 2002 to January 2009, where he was responsible for the management and direction of the nation's chemical and pollution prevention programs.

Lynn L. Bergeson is managing partner of B&C and practices extensively in all matters involving the Toxic Substances Control Act (TSCA) and related global chemical notification programs.

The date of signature is both the date of enactment and of entry into force of the amended TSCA (we will use "new" or "amended" TSCA to refer to Pub. L. No. 114-182 and "old TSCA" when referring to the prior version (Pub. L. No. 94-469)). Below we highlight a number of important changes and deadlines of which companies subject to TSCA should be aware.

Potential Revisions for Small Business Criteria

Amended TSCA Section 8(a)(3)(C) requires the Environmental Protection Agency to consult with the Small Business Administration (SBA) regarding the adequacy of the small manufacturer standards, provide for notice and comment, and make a determination as to whether revision of the standards is warranted no later than 180 days after the June 22, 2016, enactment date, or by Dec. 19, 2016.

As currently defined in 40 C.F.R. § 704.3, a small manufacturer or importer must meet either of the following standards:

- (1) *First standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$40 million. However, if the annual production or importation volume of a particular substance at any individual site owned or controlled by the manufacturer or importer is greater than 45,400 kilograms (100,000 pounds), the manufacturer or importer shall not qualify as small for purposes of reporting on the production or importation of that substance at that site, unless the manufacturer or importer qualifies as small under standard (2) of this definition.
- (2) *Second standard.* A manufacturer or importer of a substance is small if its total annual sales, when combined with those of its parent company (if any), are less than \$4 million, regardless of the quantity of substances produced or imported by that manufacturer or importer.

This definition of small manufacturer has not been revised since it was originally incorporated into the 1986 Inventory Update Rule (IUR) guidance. Using the Bureau of Labor Statistics' inflation calculation, \$4 million in 1986 is equivalent to \$8,767,000 in 2016. Given the significant differential between the monetary thresholds, it seems reasonable to conclude that the initial consultation between the EPA and the SBA will result in a decision to revise the small manufacturer standard.

While a revision of the small manufacturer definition is reasonable to expect, it will not be completed in time for the ongoing 2016 Chemical Data Reporting (CDR) cycle. It should, however, occur in time for the next CDR cycle in 2020. Depending on the timing of the promulgation of this change, it could affect other early reporting under new TSCA, such as the TSCA Inventory "reset" discussed below.

Reporting Under Section 8(a) and the Potential Expansion of CDR Reporting to Processors

As was the case under old TSCA before June 22, under new TSCA, the EPA retains the authority to apply Section 8(a) reporting to processors as well as manufacturers. The most important of the currently applicable reporting requirements under TSCA Section 8(a) is the CDR rule. The TSCA CDR rule, 76 Fed. Reg. 50816 (Aug. 16, 2011), enables EPA to collect and publish information on the manufacturing, processing, and use of certain commercial chemical substances and mixtures on the inventory. It applies only to manufacturers (note that Section 26(p)(1) makes clear that the CDR rule remains in effect). Other revisions to Section 8(a) offer additional guidance and impose new requirements on EPA that it must consider and meet in imposing future Section 8(a) reporting requirements. Section 8(a)(4) states that EPA *may* impose different reporting and record keeping requirements on manufacturers (including importers) and processors and that it *shall* include the level of detail and the manner by which use and exposure information *may* be reported. At Section 8(a)(5), the EPA is directed to avoid reporting requirements that are unnecessary or duplicative, minimize the cost of reporting and compliance for small manufacturers and processors, and impose reporting requirements to those entities "likely to have information relative to the effective implementation" of the new law.

More generally, review of these new TSCA provisions suggests several new uses for CDR-type reporting information. These include use of CDR data in Section 6(b) prioritizations and risk evaluations and for identifying chemicals for testing under the "additional" testing authority at Section 4(a)(2), including to obtain prioritization testing. This provision does not require EPA to make findings, and EPA is authorized to issue testing orders in addition to requiring testing by rulemaking and consent agreement.

The changes to the language in Section 8(a), in conjunction with new needs and uses for CDR-type information by EPA, suggest strongly that yet another round of changes will be imposed on the regulatory community under the 2020 CDR. This may not be news welcomed by the chemical community, which has been wit-

ness to significant changes in CDR reporting in every reporting cycle since 2006.

Some stakeholders will likely support the inclusion of processors under an amended CDR umbrella because of the potential to improve the level of information made available to the EPA regarding volumes, uses, and exposures associated with processing activities, and the utility of this information for purposes of the EPA's regulatory decision-making process. Requiring submission of this information also could, however, impose significant new reporting burdens on chemical processors. At this point, it is unclear whether businesses will be reporting as both manufacturers and processors, and if so, how reporting functionalities will be managed given the Congressional directive to the EPA to minimize costs to processors.

Another area to watch is the EPA's approach to Congress's mandate that the agency apply reporting requirements to entities "likely to have information relative to the effective implementation" of the Act. The EPA also will have to consider carefully how it will collect information, consistent with this requirement, from manufacturers and processors while avoiding duplicative or unnecessary reporting. The EPA could, for example, conduct an initial analysis of information reported as "not known or reasonable ascertainable" (NKRA) under the CDR, evaluate whether those information elements might be known to processors, and modify the reporting rule accordingly. The EPA also could modify the current "joint submitter" mechanism under CDR to connect manufacturer and processor information for reported chemicals.

Section 8(a)(6). Negotiated Rulemaking to Limit Inorganic Byproduct Reporting Requirements

As defined by the Negotiated Rulemaking Act of 1990 (Pub. L. No. 101-648), a "negotiated rulemaking" is defined as rulemaking through the use of a negotiated rulemaking committee, and the "negotiated rulemaking committee" or "committee" is defined as an advisory committee established by an agency (in this case, EPA) in accordance with Title 5, U.S. Code Subchapter III and the Federal Advisory Committee Act to consider and discuss issues for the purpose of reaching a consensus in the development of a proposed rule (5 U.S.C. § 562).

The EPA is required to enter into a "negotiated rulemaking" to propose a rule to limit CDR reporting requirements on manufacturers of inorganic byproducts, when such byproducts, whether generated by the byproduct manufacturer or by any other person, are subsequently recycled, reused, or reprocessed. This initiative is to occur no later than three years after enactment, or by June 22, 2019, and the final rule must be issued within three and a half years after enactment, or no later than Dec. 22, 2019. The short time between when negotiated rulemaking must begin and must be completed suggests that EPA will begin the process significantly in advance of its June 22, 2019, deadline.

A "byproduct" is defined under TSCA as a "chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture" (40 C.F.R. § 720.3(d)).

The EPA has stated that byproducts “without separate commercial value are nonetheless produced for the purpose of obtaining commercial advantage, since they are part of the manufacture of a chemical substance produced for commercial purposes” (40 C.F.R. § 720.3(r)).

For this reason, byproducts are considered a manufactured substance under TSCA and are, therefore, reportable under the CDR rule. Byproducts are exempt from CDR reporting if their only commercial purpose is use by public or private organizations that burn it as a fuel, dispose of it as a waste, or extract component chemical substances from it for commercial purposes (40 C.F.R. § 720.30(g)). This last provision will be the subject of the negotiated rulemaking.

The EPA’s current regulatory interpretation of the “*extract component chemical substances from it*” phrase applies only if the extracted chemical component in the byproduct is removed through a process that does not involve a chemical reaction. The EPA has stated the component to be extracted must exist already as a distinct chemical substance in the byproduct. When the chemical substance present in the byproduct and the chemical substance extracted from the byproduct are different chemical substances, neither the manufacture of the byproduct nor the manufacture of the extracted chemical substance qualify for the 40 C.F.R. § 720.30(g)(3) exemption (76 Fed. Reg. at 50849).

Under the EPA’s interpretation, any chemical reaction that occurs during the process to extract the subject chemical component defeats the application of the byproduct exemption, and triggers TSCA reporting for the byproduct. Industry has long argued that this interpretation discourages recycling programs that require a chemical reaction to extract commercially valuable metals or other materials from byproducts that previously were disposed of as waste. Regardless of the outcome of the process, a negotiated rulemaking offers a very promising venue for crafting a workable regulation in this complicated area. Note that the negotiated rulemaking involves relief from “reporting requirements, under this subsection [*i.e.*, Section 8(a)], for manufacturers of any inorganic byproducts,” not relief from listing the byproduct on the Inventory.

Section 8(b)(3). TSCA Inventory and Nomenclature

New TSCA specifically addresses several Inventory and nomenclature issues. We discuss each below.

Statutory Mixtures.

Under new TSCA, the EPA must treat the individual members of the categories of chemical substances identified by the EPA as statutory mixtures as being on the Inventory. These statutory mixture categories have been defined in Inventory descriptions established by EPA. Arguably, this provision is intended to clear up the somewhat unclear and controversial issue of statutory mixtures that has extended over many years. For a more detailed discussion of these issues see Lisa R. Burchi, Charles M. Auer, Kathleen M. Roberts, and Lynn L. Bergeson, “Are TSCA Section 8(b)(2) Statutory Mixture Categories Subject to Reporting Under the Chemical Data Reporting Rule?,” *Bloomberg BNA Toxics Law Reporter*, April 12, 2012. There are six categories iden-

tified for statutory mixtures, as defined in the existing guidance for “Products Containing Two or More Substances: Formulated and Statutory Mixtures” (See EPA, Toxic Substances Control Act Inventory Representation for Products Containing Two or More Substances: Formulated and Statutory Mixtures, available at <https://www.epa.gov/sites/production/files/2015-05/documents/mixtures.pdf>):

1. Cement, Portland, Chemicals;
2. Cement, Alumina, Chemicals;
3. Glass, Oxide, Chemicals;
4. Frits, Chemicals;
5. Steel Manufacture, Chemicals; and
6. Ceramic Materials and Wares.

Section 8(b)(3)(A)(iii) states that a substance that is a member of one of these categories “shall” be treated as being “included” on the Inventory. Such a statement seems to obviate the need for notification under Section 5(a) for the individual chemical components of the subject statutory mixture, but it is unclear how it will impact CDR reporting obligations.

Nomenclature.

Per Section 8(b)(3)(A)(i) and 8(b)(3)(A)(ii), the EPA must maintain the use of Class 2 nomenclature and the Soap and Detergent Association (SDA) Nomenclature System.

Multiple Nomenclature Listings.

Section 8(b)(3)(B) states that if a manufacturer or processor “demonstrates to” the EPA that a substance appears multiple times on the Inventory under different Chemical Abstracts Service (CAS) numbers, EPA *may* recognize the multiple listings as a single substance.

This language seems intended to lower the barrier to interchangeability of source-based names beyond the substance names in the SDA System. The SDA system allows manufacturers to use substances from different SDA-listed sources interchangeably when producing chemical substances identified by SDA nomenclature.

For example, under old TSCA, a manufacturer could produce a fatty acid methyl ester (FAME) biodiesel from corn oil and identify that FAME as either:

- Fatty acids, corn-oil, Me esters (CAS Registry Number (CASRN) 515152-40-6); or
- Fatty acids, C16-18 and C18-unsatd., Me esters (CASRN 67762-38-3).

The manufacturer could switch to a soybean oil source, and still manufacture Fatty acids, C16-18 and C18-unsatd., Me esters (CASRN 67762-38-3) because soybeans are identified in the SDA system as a source of “C16-18 and C18-unsatd. fatty acids.” Conversely, the manufacturer could not call the soybean FAME by the name Fatty acids, corn-oil, Me esters (CASRN 515152-40-6) because the source was soybean oil, not corn oil. The language in new TSCA can be read to allow, but not require, EPA to treat two source-based identities as interchangeable (*i.e.*, the same substance)

even when the substances are not identified using SDA nomenclature if the manufacturer can “demonstrate” that the substance “appears multiple times” on the Inventory. Note that, excluding SDA names, the EPA may argue, perhaps reasonably, that no substance “appears multiple times under different CAS numbers.”

A Senate Environmental and Public Works Committee report on S. 697 provides some additional insight into the legislative language. Note that the final text of H.R. 2576 relating to nomenclature is slightly different from S. 697, and that the joint committee report is not yet available at the time of this writing. In particular, the Senate report states:

[Treating multiple listings as a single substance] will help prevent duplicative safety assessments and determinations by ensuring that *substantially equivalent chemicals* are considered at the same time, as appropriate. The Committee believes this approach will also help enhance EPA’s ability to evaluate substances from new sources against existing substances for equivalence, enabling similar substances to rely on the Inventory listing of an existing substance (S. Rep. No. 114-67, at 20 (2015) (emphasis added)).

The “substantially equivalent” language does not appear in the text of the new law, but because there are multiple substances listed on the TSCA Inventory that could be considered “substantially equivalent,” it may be that the Senate’s intent is for EPA to consider “substantial equivalence” instead of actual “sameness” to determine if a substance is listed multiple times. Note that amended TSCA is silent on how to “demonstrate” multiple Inventory listings; new TSCA permits, *but does not require*, EPA to recognize the multiple listings as a single substance, and the substances that are being compared must both be on the Inventory (so this approach seems not to be available in the case of a *bona fide* request or new chemical notice).

Sections 8(b)(4) through (6). Inventory “Reset”

By **June 22, 2017**, (within 1 year of enactment), the EPA must publish a rule to “reset” the Inventory (Section 8(b)(4)(A)). Per TSCA Section 8(b)(6), the EPA must designate the chemicals reported under the 2016 CDR as the “interim” list of active substances. The rule also must require manufacturers and *may require* processors to notify the EPA, no later than 180 days after the final rule is published, as to which substances on the Inventory were manufactured or processed in the 10 years prior to enactment (*i.e.*, June 22, 2006, through June 21, 2016). The final notification deadline will depend on when the final rule is published, but will occur between **December 2017** and **June 2018**.

Active Substance Notification.

If a notice is received under Section 8(b)(4)(A)(i), the substance must be designated by the EPA as “active.” If no notice is received, the EPA must designate the substance as “inactive.” Inactive substances stay on the Inventory and, if subsequently intended for manufacture, import, or processing, do not trigger requirements for premanufacture notices (PMN) (per Section

8(b)(4)(A)(iv)) but, as described below, *do trigger* a requirement to notify EPA before the date of manufacture or processing.

Submitters notifying the EPA of active substances listed in the confidential portion of the Inventory must assert and substantiate an “existing claim.” Pursuant to Section 8(b)(8), a submitter cannot claim the identity of a substance as Confidential Business Information (CBI) for any substance not already listed as CBI.

If, as part of an “active substance” notice, a substance currently listed on the confidential portion of the Inventory does not receive any substantiated CBI claims for chemical identity, Section 8(b)(4)(B)(iv) requires that the EPA list the substance on the public portion of the Inventory. Inactive CBI substances remain CBI.

An updated version of the Inventory that includes active and inactive designations must be made available to the public. Although there is no deadline in new TSCA, this updated version of the Inventory will likely be published about six months after the final active substance notification deadline. We would expect a final, updated Inventory to be available by the **end of 2018**.

Activating an Inactive Substance.

Once the updated Inventory is published, Section 8(b)(5)(B) requires that manufacturers, importers, or processors notify the EPA prior to manufacturing, importing, or processing an inactive substance. New TSCA does not specify a mechanism for such notification or a required time frame, only that it occur before the date that such commercial activities occur. In an activation notice for an inactive substance on the confidential portion of the Inventory, a submitter must assert any existing CBI claim for chemical identity and further substantiate the CBI claim within 30 days, or else the substance will be activated as a non-CBI substance. Upon activation, EPA designates the substance as active, “promptly” reviews the CBI claim and associated substantiation, and may review the priority of the substance (for Section 6 review) as EPA determines necessary.

CBI Claim Review.

Within one year of compiling the active/inactive list, Section 8(b)(4)(C) requires that EPA promulgate a rule with a plan to review all claims of CBI for the chemical identity of active substances on the confidential portion of the Inventory. The CBI review rule must require manufacturers or processors to assert confidentiality claims, unless a previous claim was substantiated during a five-year period preceding a date specified by EPA.

In reviewing CBI claims, both new (*e.g.*, claims from “active notices”) and old (*e.g.*, claims from a recent Notice of Commencement), Section 8(b)(4)(C) requires that EPA determine if the claim qualifies for protection from disclosure. EPA must approve or deny each claim, but can approve part and deny part of a claim. In accordance with Section 14, CBI claims sunset after ten years (but may be renewed), although claims may sunset earlier if the submitter withdraws the claim or if EPA “becomes aware that the information does not qualify for protection from disclosure.”

EPA must complete the CBI identity claim review process within five years of publishing the Inventory reset, but may extend the review period for two additional

years if the available resources are overwhelmed by the number of claims.

Important Inventory Reset Items:

- Companies should begin to assess which substances qualify as “active” in their supply chains as they are compiling information about manufacturing, importing, and processing chemicals as required for 2016 CDR. In addition to complying with reporting obligations, companies are well advised to retain records of substances in their supply chain which are exempt from reporting under this CDR cycle. The CDR reporting, along with documentation of exempt substances, may provide much of the information that may be required by the Inventory reset rule. Stakeholders should recognize that there is no volume threshold for reporting chemicals as “active.” Furthermore, the ten-year window for the reset is considerably longer than the four-year CDR reporting cycle. A careful review of historical records will be necessary to ensure all chemicals potentially eligible for the active list are identified and considered.
- While processors may not be required to notify, it will likely be in their best interest to do so. Alternatively, they can work closely with their supplier to ensure that the requirement to report is satisfied. Regardless, processors must take care to ensure that any substances that they regularly or periodically process are on the active Inventory. While chemicals can easily be activated as described above, there could be enforcement issues if a company, for example, inadvertently processes a long-standing but infrequently used chemical (perhaps held in the company’s storage room) that has *not been* reported for the active Inventory.
- It is not clear if notifications must be substantiated to demonstrate manufacturing, importing, or processing of a substance over the ten-year window and, if required, what would constitute substantiation.

Section 8(b)(10): Mercury Inventory Provision

New TSCA added subsection (10) to Section 8(b), which requires EPA to create an inventory of supply, use, and trade of mercury and mercury compounds in the United States by **April 1, 2017**, and every three years thereafter. The goal of this provision, which also was highlighted in the Mercury Use Reduction Act of 2012, is to give EPA relevant information *on any continued use of mercury in the U.S.* with the intent of identifying opportunities for further reducing such use. This reduction could occur through proposed revisions of federal law or regulations in mercury use.

EPA must issue a final rule for periodic reporting of the manufacture of mercury or mercury-added products, or intentional uses of mercury in the manufacturing process by **June 22, 2018** (two years after enactment). To meet this deadline, EPA would need to propose a rule by **December 2017**. Entities engaged in the generation, handling, or management of mercury-containing waste will not be required to report, unless

they manufacture or recover mercury in the management of that waste.

It is important to note that the legislative text of amended TSCA under Section 8(b)(10)(A) -- Definition of Mercury states (emphasis added): In this paragraph, *notwithstanding section 3(2)(B)*, the term “mercury” means (i) elemental mercury; and (ii) a mercury compound.

TSCA Section 3(2)(B) provides exclusions for chemical substances regulated under other federal statutes, such as drugs, pesticides, tobacco, and food or food additives. The “notwithstanding” clause in the mercury definition language means that mercury and mercury compounds used as drugs, pesticides, or in uses otherwise regulated under other federal laws that are usually exempt from TSCA *will be included* within the scope of the mercury inventory and reporting provisions. Thus, the reporting that will be required under Section 8(b)(10) will apply to any and all mercury or mercury compounds, or any intentional use of mercury in a manufacturing process (e.g., as a catalyst), including those compounds or manufacturing processes used as or relevant to drugs, pesticides or for other applications.

Potentially impacted organizations should carefully monitor how EPA proceeds with implementation. The legislation defines “mercury” as elementary mercury or a mercury compound. The lack of definitional detail for “mercury compound” may be problematic given that mercury can and does occur naturally at low levels. Industry stakeholders engaged in the negotiations for the Minamata Convention on Mercury worked diligently to ensure that the definitions for mercury, mercury compound, and mercury-added products were carefully constructed to ensure that materials with naturally occurring mercury or mercury compounds contained in many minerals and metals at low levels were not captured. The Minamata Convention on Mercury is a global treaty to protect human health and the environment from the adverse effects of mercury. See <http://www.mercuryconvention.org/Home/tabid/3360/Default.aspx>.

Given the mandate to update the mercury inventory every three years, the periodic mercury manufacture/use reporting will likely be separate from the CDR under Section 8(a), which is on a four-year reporting cycle.

Conclusion

The change within Section 8 that will have the broadest impact is resetting the Inventory. If not already begun, industry stakeholders should begin working to research and prepare the list of chemicals that they intend to report as “active” when EPA proceeds with rulemaking.

Other changes that are expected to be significant include changes to Section 8(a) concerning the ability to impose different requirements on manufacturers versus processors while minimizing unnecessary or duplicative reporting, and the notation at Section 8(b)(4)(A) that EPA “may require processors” to report under the Inventory reset rule. It seems reasonable to expect that the EPA will more frequently require reporting by processors under Section 8 of the new law. In contrast, reporting by processors was very uncommon under old TSCA.

While perhaps not as immediately significant, the other potential changes under Section 8 may have long-lasting impacts on industrial stakeholders and, therefore, warrant close attention. These include a revised small business definition and the inclusion of processors in CDR.

This also may be true of the pressures being placed on confidential chemical identities of active and inactive chemicals under the provisions in Section 8 and Section 14. The fact that such claims are only available when there is already an existing claim for confidential chemical identity could have unforeseen but potentially regrettable economic consequences. This could result when, perhaps a decade or more hence, novel new uses

and applications are identified for an inactive chemical that did not have an existing claim for CBI chemical identity. The innovator would be unable to claim the identity of the substance CBI as it reenters commerce as an active chemical and, because of the limitation on CBI identity claims in new TSCA, it would not be possible to claim the chemical identity as CBI in CDR or other future Section 8(a) reporting. While the innovator could protect from disclosure other aspects of the chemical's commercialization, such as volume and uses, the mere fact that a chemical has suddenly reappeared and remains steadfast in commerce could provide foreign and domestic competitors with critical commercial information that would not otherwise be available to them.