

TSCA 2020: What You Need to Know About the Months Ahead

Stephen A. Owens & Allen A. Kacencjar

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Karen Winters

Partner, Columbus

T +1 614 365 2750

E karen.winters@squirepb.com



Stephen A. Owens

Partner, Phoenix/Washington DC

T +1 602 528 4170

E steve.owens@squirepb.com



Allen A. Kacenjar Jr.

Partner, Cleveland

T +1 216 479 8296

E allen.kacenjar@squirepb.com

TSCA Issues to be Discussed

- Risk Evaluations & Rulemakings on “First Ten” Chemical Substances
- Risk Evaluations on 20 High-Priority Chemical Substances
- Risk Evaluation Fee
- 2020 Chemical Data Reporting
- New CBI Substantiation Requirements for Substances on the TSCA Inventory

2016 TSCA Amendments

- Lautenberg Chemical Safety Act signed into law on June 22, 2016.
- Requires EPA to evaluate new and existing chemical substances to determine whether they present an unreasonable risk of injury to health or the environment under the conditions of use.
 - Prohibits consideration of costs or other non-risks factors in evaluations.
 - Requires EPA to consider potentially exposed or susceptible subpopulations in evaluating chemical substances.
 - Allows manufacturers to request risk evaluations of existing chemicals.
 - Authorizes EPA to issue administrative orders to require testing of chemicals.
- Eliminates the “least burdensome” requirement for chemical restrictions.
- Puts limits on confidential business information (CBI) claims.
- Allows EPA to charge new/higher fees for chemical reviews.
- Preempts state chemical regulations under certain conditions.
- Required EPA to designate substances as “active” or “inactive” on the TSCA Inventory.



Coming Soon: Final “First 10” TSCA Risk Evaluations

- In December 2016 EPA initiated risk evaluations on 10 substances:
 - Asbestos; 1-Bromopropane; Carbon Tetrachloride; 1,4 Dioxane; Cyclic Aliphatic Bromide Cluster (HBCD); Methylene Chloride (MC); N-Methylpyrrolidone (NMP); Perchloroethylene; Pigment Violet 29 (PV29); Trichloroethylene (TCE).
- Draft risk evaluations have been issued for all substances.
- Comment deadline has closed for all except asbestos and perchloroethylene.
 - Comments on asbestos draft due June 2, 2020.
 - Perchloroethylene draft was just issued on April 27.
 - Comments will be due 60 days from date of Federal Register notice.
- June 2020 deadline for issuance of final risk evaluations for all 10 substances.
 - But note: For asbestos, EPA plans to issue “a supplemental scope document and supplemental risk evaluation” to address legacy uses and associated disposal
 - Also, in March 2020 EPA issued a testing order requiring two companies (BASF Colors & Effects USA and Sun Chemical Corp.) to conduct testing on PV29.



Get Ready for the Next Step After Final Risk Evaluations: TSCA Section 6 Rules

- If EPA determines in the final risk evaluations that any use of a substance presents an unreasonable risk of injury to health or the environment, the agency must “immediately” begin to develop a risk management rule under TSCA section 6 to address the risk(s).
- EPA could impose a range of requirements and restrictions, including an outright ban on some (or all) of the uses.
- EPA must issue a proposed TSCA section 6 rule within one year after the final risk evaluation is issued (i.e., by June 2021).
- The final rule must be issued within 2 years after the final risk evaluation is issued (i.e., by June 2022).



Also Happening: Risk Evaluations on 20 “High-Priority” Substances

- In December 2019 EPA issued a final list of 20 high-priority substances for which risk evaluations must be conducted.
- Final scope documents for the 20 risk evaluations must be issued by late June 2020.
 - Draft scope documents were issued in April 2020.
 - Comment period closes on May 26, 2020 for 13 draft scopes:
 - 1,3-Butadiene; o-Dichlorobenzene (Benzene, 1,2-dichloro-); p-Dichlorobenzene (Benzene, 1,4-dichloro-); 1,1-Dichloroethane; 1,2-Dichloroethane; trans-1,2- Dichloroethylene; 1,2-Dichloropropane; Ethylene dibromide; 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB); 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA); Phosphoric acid, triphenyl ester (TPP); 1,1,2-Trichloroethane; Tris(2-chloroethyl) phosphate (TCEP)
 - Comment period closes on June 8, 2020 for 7 draft scopes:
 - Butyl benzyl phthalate (BBP); Dibutyl phthalate (DBP); Dicyclohexyl phthalate; Diethylhexyl phthalate (DEHP); Di-isobutyl phthalate (DIBP); Formaldehyde; Phthalic anhydride
- When the scope documents are finalized, EPA must initiate risk evaluations.
 - Risk evaluation process will take 3 to 3 ½ years.

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Show EPA the Money: TSCA Risk Evaluation Fee

- Companies that manufacture/import any of the 20 high-priority substances are subject to a \$1.35 million fee per substance to help pay for the risk evaluation.
- On January 27, 2020, EPA published preliminary lists of manufacturers and importers that are potentially subject to the fee (based on CDR and TRI data).
- Any company that manufactured or imported a high-priority substance in the five-year period preceding publication of the preliminary list (i.e., before Jan. 27, 2020) must “self-identify” by submitting a notice to EPA via the CDX system, “irrespective of whether they are included in the preliminary list.”
- Deadline to self-identify is May 27, 2020.
 - Comments also must be submitted by May 27, 2020.



“Certifying Out” of the TSCA Risk Evaluation Fee

- Companies identified on the preliminary lists may “certify out” of the obligation to pay the risk evaluation fee under two circumstances:
- If they did not manufacture/import the substance in the five-year period preceding January 27, 2020; or
- If they manufactured the substance during the five-year period preceding January 27, 2020, **but** had ceased manufacturing/importing before March 21, 2019, **and** they will not to manufacture the substance again for five years.
- Must submit the certification to EPA via the CDX by May 27, 2020.



TSCA Risk Evaluation Fee Exemptions

- On March 25, 2020, EPA announced that it will be revising the TSCA fee rule to exempt companies from the risk evaluation fee if they:
 - Import the substance in an article;
 - Produce the substance as a byproduct; or
 - Produce or import the substance as an impurity.
- Because the revisions will not be done until late 2021, EPA is exercising its enforcement discretion and will not take action against companies that fall into these three categories and do not self-identify by May 27, 2020.
 - But if a company is already on the preliminary list for a substance, the company should submit a certification to EPA by May 27, 2020 stating that it falls within one of the categories, so that EPA can remove the company before the list is finalized.
- But note: other actions are still subject to the fee:
 - No exemption for R&D.
 - No exemption for non-isolated intermediates.
 - No exemption for de minimis amount.

EXEMPT

NON-EXEMPT

Payment of the TSCA Risk Evaluation Fee

- Each manufacturer/importer is individually responsible for the risk evaluation fee, but companies may form a consortium to split the fee amount.
 - The members of the consortium should decide how to split up the fee among themselves.
 - If they cannot reach agreement on the fee split, EPA will allocate the fee among the responsible parties, generally on a per capita basis (but with adjustments/discounts for entities that qualify as small businesses).
 - If no consortium is formed or if some manufacturers/importers join the consortium but others do not, EPA will allocate the fee on a per capita basis among the non-consortium parties (with adjustments/discounts for small businesses).
 - If a consortium is formed, EPA must be notified within 60 days after the publication of the final scope of the risk evaluation (i.e., roughly by late August).
- EPA will begin sending out invoices in August 2020.
 - The fee must be paid in full not later than 120 days after EPA publishes the final scope of the risk evaluation (i.e., roughly by late October).



TSCA Chemical Data Reporting (CDR) 2020 – The Basics

- What: Requires reporting of chemical production and use data every four years.
 - The current requirement covers calendar years 2016 through 2019.
 - Separate report due for each site (“Form U”) addressing all relevant chemicals.
 - Includes annual production volume, additional manufacturing, processing and use information for 2019.
- Who: Manufacturers (including importers) of chemical substances that:
 - Are listed on the TSCA Inventory as of June 1, 2020
 - Have a production volume of $\geq 25,000$ lbs in any year between 2016-2019 at a site
 - For certain substances, have a production volume of $\geq 2,500$
- How & Where: Submitters must report electronically using EPA’s Central Data Exchange (CDX) system.
- When: Reports are due between June 1 and November 30, 2020.
- Standard: “Known to or reasonably ascertainable by” the reporter.



CDR 2020 –Applicability Overview

- Step 1 – Chemical Substance Applicability:
 - Chemical must be on the TSCA Inventory
 - Chemical must be manufactured for commercial purposes
- Step 2 – Chemical Exemptions:
 - Case-by-case analysis, can be complicated
 - Full exemptions include: Polymers, naturally occurring substances
 - Partial Exemptions include: petroleum process streams
- Step 3 – Chemical Exemption Limits:
 - Exemptions are unavailable for chemicals subject to a range of special circumstances, including those subject to Consent agreements, SNURs, Section 4 orders, Section 5 orders, Section 6 rules and certain TSCA civil actions.
- Step 4 – Manufacturer Applicability:
 - Did you manufacture the chemical in an amount that meets the reporting threshold in any year between 2016 and 2019 at a site?



CDR 2020 – Key Regulatory Changes

- Published on April 9, 2020, Effective May 11, 2020 to better:
 - Align CDR with TSCA reform,
 - Collect data that supports EPA’s new TSCA program,
 - Reduce reporting burdens to small manufacturers and processors
- Key Changes:
 - Limits CBI Claims
 - *Up front* substantiation
 - *More* substantiation required
 - Certain data *cannot* be CBI
 - Requires Recycling Information
 - Byproducts
 - Two new exemptions: (1) generated from pollution controls/boilers; (2) by Portland cement and Kraft pulping operations
 - Voluntarily seeking more byproduct information
 - Highest Level Parent Company – now includes foreign entities
 - Expands Small Business Exemption



- Get started now:
 - Review 2016 Submissions
 - Know your sites and substances
 - Cross disciplinary teamwork
- Flag key questions, gaps and concerns early
- Protect your CBI!
- Double check against prior submissions for risks and potential compliance issues.
- Leave enough time for CDX problems



New Requirements for Substantiating CBI Claims for Substances on the TSCA Inventory

- On March 6, 2020 EPA finalized a rule imposing new requirements for substantiating confidential business information (CBI) claims for substances currently listed on the TSCA Inventory.
- The rule becomes effective on May 5, 2020.
- Background
 - Under the TSCA Inventory Reset Rule, EPA has designated substances on the Inventory as either “active” or “inactive”
 - If a company submitted a Notice of Activity (NOA) Form A to designate a confidential substance as active, it had to reassert the CBI claim.
 - But substantiation of the CBI claim was not required when the NOA Form A was submitted.
 - A CBI claim likewise must be reasserted in a NOA Form B, if a company seeks to redesignate an “inactive” confidential substance to “active”.
 - Substantiation must be provided within 30 days after submitting the NOA Form B.
- The rule adds two new questions related to the susceptibility of a chemical identity to reverse engineering and sets deadlines for submitting substantiation.

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- Any company that re-asserted a CBI claim for specific chemical identity when they filed a NOA Form A – but did not substantiate the CBI claim at that time – must submit the substantiation by Nov. 1, 2020.
- If a company provided substantiation when it submitted a NOA Form A, it must supplement the substantiation to respond to the two new questions related to reverse engineering by Nov. 1, 2020.
- If a company that asserted a CBI claim in an NOA Form A fails to provide substantiation or fails to supplement its previous substantiation with answers to the two new questions by Nov. 1, EPA will deny the CBI claim.



CBI Claim in NOA Form B

- Any company that has filed a NOA Form B and submitted CBI substantiation prior to May 5, 2020 must supplement its substantiation by providing responses to the two new questions by June 4, 2020.
- If a company has not yet provided any substantiation for a NOA Form B CBI claim or submits the NOA Form B after May 5, the company must provide full substantiation, including responses to the two new questions, within 30 days after the NOA Form B was/is submitted.
- If the CBI substantiation is not timely supplemented or received, EPA will move the substance from the confidential portion of the TSCA Inventory to the public portion.



- The rule exempts any company that submitted a NOA Form A if the company has substantiated the CBI claim in a different submission to EPA less than 5 years before Nov. 1, 2020.
 - But only if the prior substantiation contains information that is responsive to all the substantiation questions (including the two new questions relating to reverse engineering).
 - Examples: substantiation for a CBI claims for chemical identity provided with 2016 or 2020 CDR submissions or with Notices of Commencement (NOCs).
- The company must provide information to EPA about the previous submission, including the submission date; submission type; and case number, transaction ID, or equivalent identifier, by Nov. 1, 2020.



EPA

U.S. Environmental Protection Agency
NOTICE OF COMMENCEMENT OF
MANUFACTURE OR IMPORT (40CFR§720.102)



Environmental Topics

Laws & Regulations

Chemical Data Reporting

- EPA must complete its review of all CBI claims by February 19, 2024.
 - But if the review cannot be completed by that date due to the number of CBI claims needing review and the available resources, EPA may extend the deadline for up to two additional years.
- If EPA approves a CBI claim, the specific chemical identity will generally be protected from disclosure for a period of 10 years from the date on which the CBI claim was first asserted by any submitter after June 22, 2016.
 - Note: CBI claims can be renewed for 10-year periods.



Questions?



Karen Winters

Partner, Columbus

T +1 614 365 2750

E karen.winters@squirepb.com



Stephen A. Owens

Partner, Phoenix/Washington DC

T +1 602 528 4170

E steve.owens@squirepb.com



Allen A. Kacenjar Jr.

Partner, Cleveland

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E allen.kacenjar@squirepb.com