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The TSCA under the Biden administration: what to expect

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Overview

The US Environmental Protection Agency (EPA) Office of Chemical Safety and Pollution Prevention (OCSPP) will be busy in 2021. Implementation of the 2016 amendments to the Toxic Substances Control Act (TSCA) will continue to dominate the Office of Pollution Prevention and Toxics (OPPT). In 2021, the EPA will need to complete outstanding risk evaluations of the 'first 10' chemicals and begin developing proposals for the section 6 risk management rules necessitated by the risk evaluations' conclusions. Given the tight statutory deadline for issuing proposed risk management rules, the complexity of the issues and the novelty of applying the new regulatory authorities, risk management decisions will likely present daunting challenges to the EPA as it sorts through the many legal and evolving policy issues at play. The EPA also now has four manufacturer-requested risk evaluations that will parallel the 'next 20' chemicals for review. The change in administration makes the next four years especially 'unpredictable', not a word the business community welcomes.

For the risk evaluations for the first 10 substances, the Biden administration is expected to take a hard look at their scopes, including how they address potentially exposed or susceptible subpopulations, as required under the TSCA. Exposures to workers and populations bordering chemical facilities are likely to receive increased attention consistent with the Biden administration's planned elevated consideration of environmental justice. Additionally, the new administration may revisit assessing exposures addressed under other EPA-administered authorities, exposures expressly not evaluated under the Trump administration in the completed and ongoing risk evaluations. These reassessments could result in the EPA's issuance of supplemental/revised risk evaluations for those completed under the Trump administration and a need to supplement or amend the scopes of the risk evaluations now under development. The EPA determinations in certain completed risk evaluations that the chemical substance does not present an unreasonable risk for some conditions of use are the subjects of litigation. Depending on the litigation outcomes, completed risk evaluations and risk evaluations under development may need to be amended and/or supplemented, substantially affecting timelines for the completion of the risk evaluations and required risk management action addressing unreasonable risks. The EPA will have to consider carefully if it will proceed with risk management on unreasonable risks

already identified and supplement as risk evaluations are reconsidered, or if the EPA will reassess the risk evaluations in their entireties. It is too soon to predict how the new OCSPP team will sort this out.

The EPA is also expected to increase use of TSCA section 4 test orders and section 8 information gathering rules to strengthen the data sets that are available to the EPA on the 20 high-priority chemicals that are undergoing risk evaluation. For new chemicals, the new administration will likely reconsider the use of non-order significant new use rules (SNURs) in lieu of consent orders and SNURs. The EPA may also seek more test data on new chemicals, although it will need to justify additional testing if such testing includes vertebrates.

Below is a more detailed review of the complicated mosaic of challenging TSCA implementation issues the Biden administration must address.

Section 6: existing chemicals

Chemicals that will be undergoing risk evaluation in 2021 are stragglers among the first 10 chemicals' initial risk evaluations required under the TSCA, among the next 20 chemicals designated as high priority or the subject of a manufacturer request for a risk evaluation under section 6(b)(4)(C)(ii) of the TSCA that the EPA has granted. The EPA selected the first 10 chemicals for risk evaluation from the 2014 Update to the TSCA Work Plan.

Under section 6(b)(4) of the TSCA, the EPA has three years to complete a risk evaluation, extendable for an additional six months. The deadline for the issuance of the risk evaluations for these chemicals, as extended by six months, was 19 June 2020. The EPA has completed risk evaluations on methylene chloride (announced on 19 June 2020), 1-bromopropane (announced on 12 August 2020), the Cyclic Aliphatic Bromide Cluster (HBCD) (announced on 25 September 2020), carbon tetrachloride (announced on 3 November 2020), trichloroethylene (TCE) (announced on 23 November 2020) and perchloroethylene (announced on 14 December 2020). The EPA released the final risk evaluation for N-methylpyrrolidone (NMP) on 23 December 2020. The EPA has stated that the remaining risk evaluations on the 'first 10' chemicals were expected by the end of 2020, but given developments in late 2020, that date slipped to 2021.

The EPA published final risk evaluations for seven of the 'first 10' chemicals in 2020. It found that numerous conditions of use for these chemicals presented unreasonable risks to health or the environment. One of the key aspects of these risk evaluations that the new administration may revisit is the EPA's exclusion of general population exposures, for example, from ambient air or drinking water, if the substance is subject to regulation under another statutory authority implemented by the EPA, such as the Clean Air Act (CAA), the Clean Water Act

(CWA), the Safe Drinking Water Act (SDWA) or the Resource Conservation and Recovery Act (RCRA). Whether excluding these exposures from the conditions of use in risk evaluations meets the statutory requirements is not settled.

The EPA did not evaluate exposures from conditions of use managed by other environmental statutes implemented by the EPA in the risk evaluations completed to date and, as such, unreasonable risk determinations for the relevant conditions of use do not account for those exposures to the general population. It explains this decision by stating in each of the completed risk evaluations that it believes 'it is both reasonable and prudent' to tailor TSCA risk evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under the TSCA. It explains further that it believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programmes is consistent with the statutory text and legislative history, particularly as they pertain to the TSCA's function as a 'gap-filling' statute, and also furthers EPA aims to use Agency resources efficiently, avoid duplicating efforts taken pursuant to other EPA programmes and meet the statutory deadlines for completing risk evaluations. It states it therefore tailored the scope of the risk evaluation for the chemical substances using authorities in sections 6(b) and 9(b)(1) of the TSCA.

It is unclear how the new administration might view this strategy. If the new administrator, Michael Regan, wishes to broaden the scope of future TSCA risk evaluations to include exposure pathways and associated risks addressed under other EPA-administered statutes and regulatory programmes, the path would seemingly be clear. There are, however, practical difficulties associated with the EPA taking steps to broaden the 'first 10' risk evaluations to cover these aspects, given resource, technical expertise and statutory timing constraints.

As an alternative, the EPA could gain experience in evaluating those exposure pathways in future risk evaluations and then apply that experience to redo or supplement the work done on the 'first 10' risk evaluations. For risk evaluations that have been completed with findings of no unreasonable risk being issued by order under section 6(i), the path would be less clear. One possible approach, where the EPA has determined by order that a chemical substance does not present an unreasonable risk and that action is the subject of litigation challenging the EPA's approach that excludes exposure pathways, would be for the EPA to settle the case, agreeing to supplement or expand the risk evaluation to include the pathways of exposure previously not considered.

Alternatively, the EPA could announce its intention to develop a supplemental risk evaluation that considers the previously excluded pathways. The approach would be similar to one being taken by the EPA in the development of the risk evaluation for asbestos, where the EPA, in

accordance with the decision in *Safer Chemicals, Healthy Families v US EPA*, 943 F.3d 397 (9th Cir. 2019) that the EPA must consider potential risks from future activities associated with past, discontinued uses (legacy uses) and associated disposals, in which the EPA is developing supplemental material to address risks from those legacy uses and associated disposal. Any risk management action based in whole or in part on consideration of risks from exposure pathways under the jurisdiction of other EPA-implemented authorities would have to withstand challenge.

'Next 20' chemical risk evaluations

On 4 September 2020, the EPA announced the availability of the final scope documents for the ongoing risk evaluations of the 20 chemicals designated as 'high-priority substances'. As required under section 6(b)(4)(D) of the TSCA, the scope document for each chemical substance includes the conditions of use, hazards, exposures and the potentially exposed or susceptible subpopulations that the EPA plans to consider in conducting the risk evaluation for the chemical substance. It published a response to comments document that summarises and responds to public comments received on the 20 draft scope documents. Not unexpectedly, the EPA makes clear that because of the decision in *Safer Chemicals, Healthy Families v EPA*,

EPA is no longer excluding legacy uses ... or associated disposal ... from the definition of 'conditions of use'. Rather, when these activities are intended, known or reasonably foreseen, these activities are considered uses and disposal, respectively, within the definition of 'conditions of use'.

Risk management

In 2021, assuming the Biden administration does not put a hold on the process to take another look at the underlying risk evaluations, the EPA will continue the development of section 6(a) risk management rules on those of the 'first 10' risk evaluation chemicals for which the EPA has found or finds unreasonable risk, as described above. Section 6(c) of the TSCA requires that the EPA propose these section 6(a) rules within one year after the final risk evaluation is published and then promulgate the final rules within one additional year. A two-year extension, less the six-month extension the EPA exercised to complete the final risk evaluations (recognising the EPA needed more than the added six months to the risk evaluations for nine of the 10 chemicals), is available for these chemicals in total for issuance of both the proposed and final rules, with justification. The EPA should be issuing proposed section 6(a) of the TSCA risk management rules for each of the 'first 10' chemicals where the EPA found unreasonable risk. These rules are expected to be complex, and so the next several years will be challenging for the EPA, as existing chemical risk management activity will proceed at a level unprecedented under TSCA.

PBTs

The EPA met the June 2019 deadline in section 6(h) of the TSCA for proposing regulatory action and released on 22 December 2020 prepublication versions of the final rules for five persistent, bioaccumulative and toxic (PBT) chemicals – decabromodiphenyl ether (decaBDE); phenol, isopropylated phosphate (3:1) (PIP (3:1)); 2,4,6-tris(tert-butyl)phenol (2,4,6-TTBP); hexachlorobutadiene (HCBD); and pentachlorothiophenol (PCTP) the five final rules were issued on 6 January 2021 in the Federal Register. One of the five is PIP (3:1), a commonly used plasticiser, flame retardant and anti-wear additive, among other uses. The rule prohibits the processing and distribution in commerce of PIP (3:1), and the use of products or articles containing the chemical substance, for all uses, except for certain exemptions. The prohibitions were effective on 8 March 2021. Importantly, the rule does not allow sell-through opportunities for products already in commerce.

As 8 March approached, the EPA learned that regulated industries recognised they had not understood the diversity of products containing PIP (3:1). As the deadline approached, regulated entities realised, to their horror, that the rule applies to hundreds if not thousands of electronic articles. Electronics manufacturers were especially concerned as, the EPA noted, the prohibition on PIP (3:1) could 'impact articles used in a wide variety of electronics, from cell phones, to robotics used to manufacture semiconductors, to equipment used to move COVID-19 vaccines and keep them at room temperature'. Industry stakeholders urgently informed the EPA that the prohibition on processing and distribution of PIP (3:1) could adversely impact commerce and emphasised that the complexity of international supply chains makes locating the presence of PIP (3:1) in components challenging. In response, the EPA announced its decision to exercise enforcement discretion regarding the prohibitions on processing and distribution of PIP (3:1) for use in articles and the articles to which PIP (3:1) has been added. The PIP (3:1) cautionary tale demonstrates the new reality: the TSCA is every bit as commercially consequential for article manufacturers as it is for industrial chemical manufacturers.

Section 5: new chemicals

In 2020, the EPA made significant progress in resolving older cases (defined as those more than six months past the submission date). The EPA continues to use 'non-order SNURs' in lieu of section 5(e) orders for cases in which the EPA does not find unreasonable risk under the intended conditions of use. The approach, still controversial to some stakeholders, offers administrative streamlining because it reduces the number of section 5(e) orders that the EPA must produce while implementing SNUR requirements that would presumably have been required under section 5(f)(4) after an order is signed. The EPA also continued its efforts to address backlogged SNURs. It is unclear how the Biden administration will view this construct, and it may revise its approach and rely on consent orders with conforming SNURs.

While the New Chemicals Programme has made progress, it still has a way to go. The EPA needs to settle on more predictable and consistent criteria for what is likely or not likely and what is reasonably foreseeable (as opposed to what is imaginable). The new administration will need to grapple with these terms from a position of trust and give stakeholders confidence that the EPA decisions are properly supported by both the science and the law. Unfortunately, the EPA did the opposite on 29 March 2021, when it announced two policy changes. Under the first policy change, OPPT will no longer employ the 'non-order SNUR' construction to regulate new chemicals without an order. The second change is the EPA no longer views use of personal protective equipment (PPE) as 'reasonably foreseeable'. If EPA proceeds to issue orders for every premanufacture notice (PMN) that may present a risk if workers do not take routine protective measures, then the EPA will be required to regulate nearly every PMN in which the EPA identifies a hazard other than 'low hazard' for health and ecotoxicity, as was the EPA's practice when the Lautenberg Amendments were passed in 2016. That would mean that the EPA will be implementing the TSCA as a hazard-based law, instead of the clear risk-based law that it is.

The EPA plans on issuing in October 2021 a final rule it proposed in July 2016 to amend aspects of the SNURs at Part 721 of 40 CFR that pertain to new uses of chemicals, including, among others, provisions addressing 'Protection in the Workplace' and the 'Hazard Communication Programme'. According to the EPA, this action would align, where possible, the EPA's regulations with the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (HCS) regulations at section 1910.1200 of 29 CFR. As this action has been delayed repeatedly, whether the rule is an EPA priority, or will be under the new administration, is unclear.

Section 4: testing

The EPA issued its first TSCA testing action since the passage of the Lautenberg Amendments to the TSCA with the issuance on 28 February 2020 of TSCA section 4(a)(2) test orders on Pigment Violet 29 (PV29). The testing required under the orders is to inform the development of the section 6(b) of the TSCA risk evaluation of the chemical, which is among the 'first 10' chemicals identified by the EPA for risk evaluation under section 6(b) of the TSCA. The tests ordered by the EPA address uncertainties in the draft risk evaluation of PV29 highlighted by the TSCA Science Advisory Committee on Chemicals (SACC) and public comments, and they are of the type that could be conducted in a relatively short time period. Specifically, the test orders required testing to confirm the solubility of PV29 and worker respirable dust monitoring of the chemical in the manufacturing facility.

The EPA announced on 15 January 2021 that it has issued test orders under section 4 to obtain additional data on nine of the next 20 chemicals undergoing risk evaluation. According to the EPA, companies subject to the test orders may provide the EPA with existing data or may conduct new tests. Companies may also form consortia to

consolidate costs and burden and to avoid unnecessary duplication of testing.

Alternative test methods

Section 4(h)(1) of the TSCA requires the EPA to reduce and replace, to the extent practicable, the use of vertebrate animals in the testing of chemical substances or mixtures. The EPA is also required to promote the development and incorporation of alternative test methods or strategies that do not require new vertebrate animal testing. In 2018, the EPA, as required by section 4(h)(2) of the TSCA, published the Strategic Plan to Promote the Development and Implementation of Alternative Test Methods within the TSCA Programme. This section also requires the EPA to provide a periodic progress report on the implementation of the Strategic Plan to Congress – and the EPA must issue its first progress report in June 2021.

Sections 8 and 14: reporting and confidential information

The EPA plans to propose a section 8(a) TSCA information collection rule in the Spring of 2021 to require one-time reporting for per- and polyfluoroalkyl substances (PFAS) manufactured (including imported) after 1 January 2011. This is in furtherance of a requirement under section 7351 of the National Defense Authorization Act for Fiscal Year 2020 that amended section 8(a) of the TSCA, which requires the EPA, not later than 1 January 2023, to promulgate a rule requiring each person who has manufactured a perfluoroalkyl or polyfluoroalkyl chemical in any year since 1 January 2011, to submit to the EPA a report that includes, for each year since 1 January 2011, the information described in section 8(a)(2)(A)–(G) of the TSCA.

Additionally, in November 2021, the EPA intends to issue a TSCA section 8(a) rule to gather information on certain chemicals on the 2014 Update to the TSCA Work Plan, including occupational, environmental and consumer exposure information to inform TSCA prioritisation and risk evaluation. Section 8(a) of the TSCA authorises the EPA to collect a wide range of information from manufacturers (including importers) and processors of chemical substances; it is unclear, however, specifically who would be required to report, what chemicals would be the subject of reporting and what information would be required. The Biden administration is likely to move forward with this action as planned.

The Fall 2020 Regulatory Agenda also reflects the EPA's plan to issue a final TSCA section 8(d) health and safety data reporting rule in the Spring of 2021 for the 20 high-priority chemicals now undergoing risk evaluation under section 6(b) of the TSCA and for 30 organohalogen flame retardant chemicals being evaluated by the Consumer Product Safety Commission (CPSC). This action would require chemical manufacturers and importers of these substances to report lists and copies of studies on health effects, environmental effects, environmental fate and

occupational, general population and consumer exposure for these chemicals. Given the timeline for the EPA's issuance of the final risk evaluations for the 20 'high-priority' chemicals as described above, the EPA will need to review and assimilate quickly, as appropriate, the information reported under the rule to inform the development of the risk evaluations for the chemicals.

Chemical Data Reporting Rule

On 9 April 2020, the EPA published a final TSCA section 8(a) rule amending the Chemical Data Reporting (CDR) rule, 85 Fed. Reg. 20122. According to the EPA, the amendments are intended to reduce the burden for certain CDR reporters, improve the quality of CDR data collected and align reporting requirements with certain Lautenberg Amendments. Additionally, the rule extended the reporting period for CDR data submitters from 30 September 2020 to 30 November 2020, to provide additional time for the regulated community to familiarise themselves with the amendments and to allow time for reporters to familiarise themselves with an updated public version of the reporting tool.

Section 26: administration of TSCA – fees rule

Under section 26(b) of the TSCA, as amended, the EPA has authority to collect fees from chemical manufacturers and importers to defray a portion of the EPA costs associated with implementation efforts. The TSCA Fees Rule requires payment of fees for eight categories of fee-triggering events under the TSCA, including EPA-initiated risk evaluations under section 6 of the TSCA. Under the Fees Rule, the EPA is required to prepare a preliminary list of manufacturers subject to fee obligations for EPA-initiated section 6 risk evaluations. The EPA published a Federal Register notice on 27 January 2020, identifying the preliminary lists of manufacturers (including importers) of the 20 high-priority chemical substances for risk evaluation for which fees will be charged under the TSCA Fees Rule. 85 Fed. Reg. 4661. During the comment period, manufacturers (including importers) were required to self-identify as manufacturers of a high-priority substance, irrespective of whether they were included on the preliminary lists identified by the EPA.

On 25 March 2020, the EPA announced that it would consider the development of a proposed rule that would look at potential exemptions to the TSCA Fees Rule in response to stakeholder concerns about implementation challenges. The EPA stated that by considering a proposal to narrow the broad scope of the current requirements, it 'could significantly reduce burden on potentially thousands of businesses across the country while maintaining the ability to successfully implement the Lautenberg Act amendments' to the TSCA to protect human health and the environment. According to the EPA, it planned to initiate a new rule-making process to consider proposing exemptions to the current rule's self-identification requirements associated with EPA-initiated

risk evaluations for manufacturers that import the chemical substance in an article, produce the chemical substance as a by-product or produce or import the chemical substance as an impurity.

In the 25 March 2020 announcement, the EPA stated additionally that 'in light of the extremely unusual circumstances of this situation and the undue hardship imposed on certain businesses who would be required to collect and report information' under the TSCA Fees Rule, it issued a 'no action assurance' for the three categories of manufacturers (ie for manufacturers that import the chemical substance in an article; produce the chemical substance as a by-product or produce or import the chemical substance as an impurity). More specifically, the EPA stated that it 'will exercise its enforcement discretion regarding the self-identification requirement for the three categories of manufacturers' for which the EPA intends to propose an exemption. The EPA suggested that businesses that are erroneously on the preliminary lists of fee payers or fall into one of the three categories discussed above should see its frequently asked questions (FAQs) for more information about how to certify as such to the EPA and to avoid fee obligations.

On 4 September 2020, the EPA published a Federal Register notice announcing the 'final' lists of manufacturers of the 20 high-priority chemical substances for risk evaluation for which fees will be charged under the Fees Rule, 85 Fed. Reg. 55283. In that notice, the EPA stated that the

TSCA Fees Rule provides EPA flexibility to refine the final list of manufacturers in a manner that is reasonable and prudent, in light of statutory and regulatory obligations related to TSCA risk evaluations and associated fee payment obligations. As such, the Agency decided to not charge a fee to those importers who were only importing small quantities of the 20 [high-priority substances] for research and development purposes only.

On 25 November 2020, the EPA released updates to the lists, stating that the updated list includes additional

manufacturers not identified on the final list of companies and removes manufacturers that self-identified in error or imported the chemical solely for the purpose of Research and Development (R&D). The EPA stated further that it is committed to ensuring the list is accurate and plans to use the updated list to begin invoicing for fees. It added that, owing to the public health emergency, the EPA is exploring options for payment flexibilities; payment options had been advocated by certain prospective fee payers. Under 40 CFR section 700.45(g)(3)(iv) of the Fees Rule, fee payments were due on 2 January 2021, 120 days from publication of the final scopes of the risk evaluations for the 20 high-priority chemical substances now undergoing risk evaluation. We are aware, however, that at least certain EPA invoices received by manufacturers required to pay a fee required payment of only one-third of the fee by 2 January 2021, with the remaining amounts due at a later date. To the extent this approach is being applied uniformly, the deferral of two-thirds of the payment to a later date will be viewed by prospective fee payers as a welcome development, we believe.

The EPA released a revised Fees Rule on 21 December 2020. The proposed rule describes the proposed modifications to the TSCA fees and fee categories for fiscal years (FY) 2022, 2023 and 2024 and explains the methodology by which these TSCA fees were determined.

Conclusion

As noted at the beginning of this article, OCSPP will be busy in 2021, and for years thereafter. On that point, there is no debate. There will be plenty of debate, however, about whether and how the new administration will fundamentally revisit core aspects of the EPA's TSCA implementation programme, particularly as to risk evaluation, and how the TSCA will be instrumental in addressing core components of the Biden administration, environmental justice and climate change. Stay tuned.