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OCTC Ohio Chemistry Technology Council

2020 Chemicals Workshop Webinar Series
TSCA 4.0: Now What?

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Welcome

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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.
  - Authorizes EPA to issue administrative orders to require testing of chemicals.
- Eliminates the “least burdensome” requirement for chemical restrictions.
- Allows EPA to charge new/higher fees for chemical reviews.
- Preempts state chemical regulations under certain conditions.

What's Up with the "First 10" TSCA Risk Evaluations?

- On December 19, 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-Methylpyrolidone (NMP); Perchloroethylene; Pigment Violet 29 (PV29); Trichloroethylene (TCE).
- TSCA imposes a 3-year deadline on EPA to complete a risk evaluation.
  - But gives EPA the ability to extend the deadline for up to 6 months
- EPA missed the December 2019 deadline for all the risk evaluations.
  - EPA missed the extended June 2020 deadline for 9 of the 10 risk evaluations.
- EPA issued only one final risk evaluation by the June deadline.
  - Methylene Chloride (MC) – completed on June 19.
  - NGOs have filed a lawsuit challenging EPA's "no unreasonable risk" determination for several uses of MC.
- No timeline for when EPA will finalize the remaining 9 risk evaluations.

What's Causing the Delay?

- Drafts for some risk evaluations were issued very late.
  - Especially asbestos and perchloroethylene.
  - Delayed public comments and peer review by the TSCA SACC.
- Extensive substantive comments on some risk evaluations.

- EPA has received criticism from the SACC and the NAS – as well as NGOs and industry groups -- for its "systematic review" process.
  - The SACC also criticized EPA's lack of data and assumptions in some risk evaluations.
- EPA has to consider legacy uses due the 9th Circuit ruling in Nov. 2019.
  - EPA recently said that it will address legacy uses in the HBCD risk evaluation.
  - For asbestos, EPA plans to issue "a supplemental scope document and supplemental risk evaluation" to address legacy uses and associated disposal.
- EPA recently received data on PV29 in response to the TSCA §4 testing order that EPA issued in March 2020.
- EPA recently received several NMP studies.

What Happens When Risk Evaluations Are Late?

- Preemption
  - "Pause preemption" does not apply to the first 10 risk evaluations.
    - Under TSCA §16, for the next risk evaluations, preemption will begins on the date that the risk evaluation scope is defined and ends "on the date on which the *deadline … for completion of the risk evaluation expires*, or on the date on which the Administrator publishes the risk evaluation …, *whichever is earlier*."
  - For first 10, preemption applies only when EPA issues final TSCA §6 risk management rule.
  - But the delay of a final risk evaluations means a delay in the final §6 rule, which gives states more time to act (and also cuts into EPA's time to issue the §6 rule).
- Delay in risk evaluations may be (indirectly) delaying the final scope documents for the next 20 risk evaluations.
  - Which also delays pause preemption for these substances.
- Delay is creating uncertainties, including what happens if EPA leadership changes after upcoming election.
  - Rulemakings, risk evaluations and outcomes of lawsuits could be determined by new officials.

What Issues Have Been Raised Regarding the Risk Evaluations?

- EPA's exclusion of uses in the risk evaluations.
  - Exclusion of legacy uses and associated disposal.
  - Exclusion of uses regulated by EPA under other statutes.
  - Exclusion of some subpopulations.
  - Assumptions about exposures and hazards.

- *Safer Chemicals, Healthy Families v. EPA,* No. 17-72260 (9th Cir. Nov. 14, 2019)
  - Ruled that EPA must consider legacy uses and associated disposal of substances.
  - Can be read to say that while EPA has discretion to determine the conditions of use for a substance, EPA cannot exclude those uses once they have been determined.
  - "If EPA does, in the future, fail to consider all conditions of use together in completing a risk evaluation, and if Petitioners are harmed by that failure, then Petitioners may, under TSCA, seek review of EPA's "no unreasonable risk" determination."
- NGOs and labor groups have filed a petition challenging the methylene chloride risk evaluation.
  - *Neighbors for Environmental Justice v. EPA*, No. 20-72091 (July 16, 2020).

What Happens Next After a Risk Evaluation is Finalized?

- Determination of Unreasonable Risk
  - If EPA determines 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 §6 to address the risk(s).
  - Determination is not a "final agency action"; only the TSCA §6 rule is appealable.
  - 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 §6 rule within one year after the final risk evaluation is issued.
  - The final §6 rule must be issued within 2 years after the final risk evaluation is issued.
  - EPA may extend the deadline by 2 years.
    - But extensions for risk evaluations count against this.

- Determination of No Unreasonable Risk
  - A "no unreasonable risk" determination must be made by an order.
  - The order is a final agency action that is judicially reviewable.

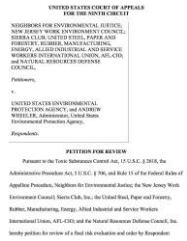
Neighbors for Environmental Justice, et al. v. EPA

Who: Unions and environmental NGOs, including Sierra Club and NRDC.

Where: The United States Court of Appeals for the Ninth Circuit

When: Filed on July 16, 2020

What:



UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NEIGHBORS FOR ENVIRONMENTAL JUSTICE; NEW JERSEY WORK ENVIRONMENT COUNCIL; SIERRA CLUB; UNITED STEEL, PAPER AND FORESTRY, RUBBER, MANUFACTURING, ENERGY, ALLIED INDUSTRIAL AND SERVICE WORKERS INTERNATIONAL UNION, AFL-CIO; and NATURAL RESOURCES DEFENSE COUNCIL,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; and ANDREW WHEELER, Administrator, United States Environmental Protection Agency,

Respondents.

PETITION FOR REVIEW

Pursuant to the Toxic Substances Control Act, 15 U.S.C. § 2618, the Administrative Procedure Act, 5 U.S.C. § 706, and Rule 15 of the Federal Rules of Appellate Procedure, Neighbors for Environmental Justice; the New Jersey Work Environment Council; Sierra Club, Inc.; the United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO; and the Natural Resources Defense Council, Inc. hereby petition for review of a final risk evaluation and order by Respondent

- EPA issued its (753-page!) final risk evaluation for methylene chloride on June 19, 2020 – the first under the amended TSCA.
- EPA determined that 47 commercial, industrial and consumer uses posed "unreasonable risk" and 6 uses did not.
- The unreasonable risk findings trigger EPA's statutory duty to establish risk management measures for those 47 uses.
- Petitioners' notice generally challenges EPA's determination that "methylene chloride does not present an unreasonable risk of injury to health or the environment under certain conditions." It also contends that EPA "declin[ed] to consider certain uses and pathways" that create exposures/risks.

Threshold Question – Ripeness & Scope

- Is what EPA did “final agency action” subject to judicial review?
- TSCA provides that a determination “that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be a final agency action . . .”. 15 U.S.C. § 2605(i)(1).
- In the final risk evaluation, EPA recognizes that its six “no unreasonable risk” determinations… are considered to be final agency action effective on the date of issuance of this order.”
- According to EPA, the unreasonable risk determinations for the remaining 47 uses “are not considered final agency action” under TSCA §6(i)(2).

Key Arguments and Issues

- Use-Specific Analysis:
  - In conducting risk evaluations, “EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of use within the scope of the risk evaluation.” 40 CFR 702.47
  - Must EPA make one unified determination? The Agency contends its “use-by-use” approach is consistent with TSCA § 6(b)(4)(A), which requires it to conduct evaluations “to determine whether a chemical substance presents an unreasonable risk . . . under the conditions of use.”
- General Population Risk Review:
  - Petitioners contend EPA “ignor[ed] all methylene chloride exposures and risks to the general public.”
  - EPA acknowledges it “did not evaluate hazards or exposures to the general population” but believes its approach was appropriate.
  - Calling TSCA a “gap filling statute”, EPA found it “both reasonable and prudent to tailor TSCA risk evaluations” where, as here ”exposures to the general population via surface water, drinking water, ambient air and sediment pathways falls under the jurisdiction of other environmental statutes….”
  - EPA cited TSCA § 6(b)(4)(D), which requires EPA to publish “the scope of the risk evaluation” and § 9(b)(1), which mandates that if EPA determines that a risk could be eliminated or reduced under other EPA-administered laws, it “shall use such authorities to protect against such risk” unless it determines it is in the “public interest” to do so under TSCA.

Key Arguments – the Role of PPE

- EPA "generally assumes compliance with OSHA requirements for protection of workers." As applied here, "for each condition of use of methylene chloride with an identified risk to workers, EPA assumes, as a baseline"
  1. The use of a respirator with a PF of 25 or 50; and
  2. The use of gloves with PF of 5 and 10 in commercial settings and gloves with PF of 5 and 20 in industrial settings.
- EPA's unreasonable risk determinations were then prepared to "reflect the severity of the effects associated with the occupational exposures to methylene chloride" considering "the PPE that EPA assumes."
- The unions have been critical of that approach. The contend that EPA's approach:
  - "Assumed PPE use despite empirical evidence to the contrary"
  - "Assumed PPE use despite…the lack of mandates" for its provision and use
  - Disregards the "longstanding industrial hygiene hierarchy of controls that places PPE as the last resort, to be used only *after* employers have taken all necessary steps to eliminate or reduce the presence of toxic chemicals in the workplace."

The Path Forward

- Petitioners' brief is due on October 5, 2020 and Respondent's Brief is due on November 3, 2020. The Halogenated Solvents Industry Alliance has moved to intervene and others are likely to do so. Thus, the briefing schedule will likely require adjustment.

- Oral argument and a decision are not likely before the inauguration in January 2021 – possibly giving EPA the chance to revise its approach if a new Administration sees things differently.

What About the Risk Evaluations on the 20 "High-Priority" Substances?

- On December 20, 2019 EPA issued a final list of 20 high-priority substances for which risk evaluations must be conducted.
  - 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); Butyl benzyl phthalate (BBP); Dibutyl phthalate (DBP); Dicyclohexyl phthalate; Di-ethylhexyl phthalate (DEHP); Di-isobutyl phthalate (DIBP); Formaldehyde; Phthalic anhydride.
- TSCA imposes a 6-month deadline on EPA to issue the scope document for a risk evaluation (i.e., by June 20, 2020).
- Draft scope documents were issued in April 2020, but EPA has not finalized any of the scope documents yet.
- When the scope documents are finalized, the risk evaluations will begin.
  - Pause preemption also will begin.
  - Risk evaluation process will take 3 to 3 ½ years.
    - This includes the scope document.

When Do You Have to Pay the TSCA Risk Evaluation Fee?

- In January 2020 EPA published preliminary lists of manufacturers and importers that are potentially subject to the $1.35 million fee for each of the upcoming 20 risk evaluations.
  - Deadline to self-identify or certify out was June 15, 2020.
- The fee must be paid in full via CDX not later than 120 days after EPA publishes the final scope of the risk evaluation.
  - But because the final scope documents have not yet been issued, the payment deadline is not yet known.
  - Also, EPA has said that the final list of companies subject to the fee would be published concurrently with release of the risk evaluation scope documents.
  - But because the final scope documents have not yet been issued, EPA has not released the final list of companies required to pay the fee.
  - EPA had said that it would send out invoices via CDX within roughly 60 days after the final lists are released.
  - No refunds!

Are There Exemptions to the Risk Evaluation Fee?

- 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 fall 2021, EPA is exercising its enforcement discretion and will not take action against companies that fall into these three categories and did not self-identify by the deadline.
  - But the "No Action Assurance" expires on Sept. 30, 2021 or the effective date of the final rule, *whichever is earlier*.
- And 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.

What Should You Watch For?

- Rule to revise EPA's process for reviewing TSCA §5 PMNs.
  - Proposed rule in Sept. 2020.
- TSCA §8(a) rule to collect information on 2014 Work Plan Chemicals.
  - Proposed rule in Nov. 2020.
- Rule to provide exemptions from TSCA risk evaluation fee.
  - Proposed rule in Dec 2020.
- EPA "secret science" rule.
  - Goal to finalize by the end of 2020.
  - Rule supposedly will be "tailored" for TSCA implementation.
- TSCA §6 rules for 5 PBT substances.
  - Must be finalized by Dec. 22, 2020.

- EPA response to industry petition for TSCA §6 procedural rule (due Sept. 1).
- Pressure by NGOs for EPA to be more aggressive in seeking data for the next 20 risk evaluations.
  - Push for voluntary requests to industry backed up by TSCA § 11 subpoenas.

Don’t Forget About These!

- New TSCA PFAS SNUR effective Sept. 25, 2020.
  - Prohibits a wide range of uses retroactively as of the date when the SNUR was initially proposed on Jan. 21, 2015.
    - If a company commenced any of the uses after Jan. 21, 2015, the company must cease the uses and submit a SNUN to EPA if it wants to continue them.
    - The SNUR also prohibits all uses of a certain group of PFAS substances as of Dec. 31, 2015 (because they supposedly were phased out by that date).
    - Does not exempt imported articles.
    - Recent controversy because the FR published version differs from the prepublication copy.
- CBI substantiation deadline: Nov. 1, 2020.
  - 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.
  - If a company provided substantiation when it submitted a NOA Form A, it must supplement the substantiation to respond to two new questions related to reverse engineering.
- TSCA CDR reporting deadline: Nov. 30, 2020.
  - Various new reporting requirements.

Questions?

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